

**DE NOVO CLASSIFICATION REQUEST FOR  
PARATHYROID DETECTION (MODEL PT EYE) SYSTEM**

**REGULATORY INFORMATION**

FDA identifies this generic type of device as:

**Autofluorescence detection device for general surgery and dermatological use.** An autofluorescence detection device for general surgery and dermatological use is an adjunct tool that uses autofluorescence to detect tissues or structures. This device is not intended to provide a diagnosis.

**NEW REGULATION NUMBER:** 21 CFR 878.4550

**CLASSIFICATION:** Class II

**PRODUCT CODE:** QDF

**BACKGROUND**

**DEVICE NAME:** Parathyroid Detection (Model PTeye) System

**SUBMISSION NUMBER:** DEN170056

**DATE OF DE NOVO:** September 27, 2017

**CONTACT:** AiBiomed, Corp.  
107 West Gutierrez Street  
Santa Barbara, CA 93101

**INDICATIONS FOR USE**

The AiBiomed Parathyroid Detection System (PTeye) is an adjunctive tool intended to aid in the identification of parathyroid tissue by confirming parathyroid tissue already visually located by the surgeon.

**LIMITATIONS**

The sale, distribution, and use of the Biomed Parathyroid Detection System (PTeye) are restricted to prescription use in accordance with 21 CFR 801.109.

The AiBiomed Parathyroid Detection System (Model PTeye) has no contraindications.

Due to limitations in parathyroid detection of autofluorescence by the PTeye System in certain disease states, the device is not recommended for use in patients with secondary hyperparathyroidism and in patients with parathyroid cysts.

The PTeye System is intended to be an aid in the identification of parathyroid tissue and not as a parathyroid locator. The use of this device has not been evaluated as a parathyroid tissue locator.

Due to a small sample size, limited clinical data is available regarding the safety and effectiveness of the PTeye System for rare disease states such as tertiary hyperparathyroidism, concomitant thyroid-parathyroid diseases, malignant parathyroid diseases, or other circumstances when prophylactic thyroidectomies are performed in individuals at high-risk for certain diseases such as MEN2A.

The PTeye requires the probe to be in direct contact with the tissue of interest for proper signal recording as its detection depth is only a few millimeters. If parathyroid tissue is covered by fat or other tissues, the fat and tissues must be manually moved out the way and/or the probe maneuvered around these tissues to make direct contact with area of interest.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

## **DEVICE DESCRIPTION**

The Parathyroid Detection (PTeye) System aids surgeons in differentiating parathyroid tissue during common surgical procedures. The handheld probe assembly includes one glass fiber-optic element that emits non-ionizing radiation at 785 nm in the near IR range (NIR) and one fiber optic detector element that collects and transmits the fluorescence emitted by the tissue to a photo detector.



The Parathyroid Detection (PTeye) System consists of the following components:

1. A console that includes:
  - An LED display that indicates if the laser is on.
  - A display for visual feedback.
  - A speaker for auditory feedback.

The console is multiple patient reusable device.

2. A handheld fiber-optic probe assembly that interfaces into the console unit using two unique connectors. One connector plugs into the laser output and the other plugs into the photo detector input (fluorescent signal). Fiber optic is sterile single use device.
3. A foot pedal attached by a cable to the rear of the unit, used to control power to the laser and initiate data collection.
4. An external power supply and power cord that plugs into the power supply.

The single use ethylene oxide (EtO) sterilized fiber-optic probe will also be sold separately.

Tissue detection is based on the ratio of the fluorescent response of parathyroid to thyroid tissue; with the assumption that the fluorescence of thyroid tissue is much lower than parathyroid.

During surgery, five thyroid data points are collected by touching thyroid tissue with the probe assembly. The system calculates a baseline median for the thyroid tissue based on those points.

The baseline value establishes a reference point for distinguishing parathyroid tissue, which produces a higher level of fluorescence.



Once the baseline thyroid value has been calculated, a new operational screen will display to support continuous parathyroid search mode. To operate in this mode, the foot switch must be pressed in order to activate the laser. When laser emission is taking place, the LASER ON LED at the front of the system will illuminate. Responses indicating parathyroid tissue are communicated to the user through a bar graph, a detection percentage, a detection ratio, and audio feedback. The highest percentage (100%), full bar graph, and the highest frequency beeps indicate 2.5-times the median of the 5 thyroid measurements taken during the baseline stage. The on-screen bar graph and detection percentage, and detection ratio correlate directly with the audio. When using the probe on non-parathyroid tissue, the display shows mostly yellow and a low detection ratio. When using the probe on parathyroid tissue, the display feedback shows primarily green and a high detection ratio.



Table 1: PTeye Regulatory Information

Device Trade/Proprietary Name	Parathyroid Detection (Model PTeye) System
Device Common Name	Parathyroid Autofluorescence Detection Device
Device Class	Class II
Classification Regulation	878.4550
Product Code	QDF

**SUMMARY OF NONCLINICAL/BENCH STUDIES**

**BIOCOMPATIBILITY/MATERIALS**

The PTeye fiber-optic assembly will be in direct contact with organ tissue. The sterile PTeye fiber-optic assembly was tested per FDA guidelines for biocompatibility and ISO 10993-1 according to FDA guidance document, “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process’”. The testing showed that the optical probe passed the biocompatibility requirements for cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, and material-mediated pyrogenicity.

The PTeye fiber-optic assembly was tested for Limulus Amebocyte Lysate (LAL) evaluation for three product lots on the final product, post-sterilization. The results show that the test article met the requirement of less than 20 EU/device. In addition, the LAL endotoxin testing will be conducted on 3 samples as part of each product lot release criteria.

**STERILITY/PACKAGING/ SHELF LIFE**

The PTeye optical probe is a sterile, single use component of the device system. The cartridge is sterilized using EO sterilization and sterilant residuals were quantified and under the acceptable limits for EO and ethylene chlorohydrin (ECH). The sterilization method was validated per ISO 11135:2014 (Sterilization of health care products -- Ethylene oxide: “Requirements for development, validation and routine control of a sterilization process for medical devices”). The Sterility Assurance Level (SAL) for the optical probe is 10<sup>-6</sup>.

The primary packaging consists of one probe assembly seated and secured inside an inner tray which is heat sealed to a Tyvek lid. The sealed primary packaged probe is placed inside a poly/Tyvek pouch which is heat sealed. The sealed outer pouch is placed inside the bottom half of the unit box. The top half of the unit box covers the bottom half of the unit box and the seals of the unit box are secured with tamper proof seals.

The shelf-life of the optical probe was evaluated after accelerated aging equivalent to one year. The cartridge was evaluated by visual inspection, peel test, and bubble leak testing. The test article met the acceptance criteria for each test.

### **ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY**

The following Electrical/Mechanical/Thermal Safety, and electromagnetic compatibility (EMC):

- IEC 60601-1: 2005 +CORR.1:2006+CORR.2: 2007 + AM1:2012 or IEC 60601-1:2012 with US deviations, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2: 2007 (Edition 3), Medical electrical equipment Part 1-2 – General requirements for basic safety and essential performance – Electromagnetic compatibility.
- IEC 60601-1-6: Collateral Standard: Medical electrical equipment Part 1-6 – General requirements for basic safety and essential performance – Usability.

### **LASER/LIGHT SAFETY**

The following laser safety testing has been performed:

- IEC 60825-1: Safety of laser products - Part 1: Equipment classification and requirements

### **MAGNETIC RESONANCE (MR) COMPATIBILITY**

Device is not compatible for Magnetic resonance (MR) environment.

### **SOFTWARE**

The software controls the PTeye system hardware including the laser firing after pressing the foot-pedal. It calculates the background level based on five data points from thyroid tissue and determines the median values of those points. It then calculates the ratio of autofluorescence signal from the background level to demonstrate if the tissue is parathyroid or not.

The software GUI includes an on-screen bar graph, detection percentage and detection ratio which correlate directly with the audio feedback. When using the probe on non-parathyroid tissue, the display shows mostly yellow and a low detection ratio. When using the probe on parathyroid tissue, the display feedback shows primarily green and a high detection ratio. The audio feedback for non-parathyroid tissue sounds with slow beep frequency (one beep per second). As the ratio of autofluorescence to background increases, the beeps are emitted more rapidly.

Device does not have wireless capability or a communication port.

The agency considers the software to be a moderate level of concern (LOC) because inadvertent software errors could result in injury to the patient or delay in procedure time.

All of the elements of software and cybersecurity information as outlined in FDA’s guidance documents “*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*” (issued May 11, 2005) and “*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*” (issued June 14, 2013) were provided.

Overall, the software documentation included in the De Novo request is in sufficient detail to provide reasonable assurance that the software will operate in a manner described in the specifications.

**PERFORMANCE TESTING – BENCH**

Test	Purpose	Acceptance Criteria	Results
<b>Short term variation in laser intensity</b>	To demonstrate the influence of short term variation in laser intensity on the device performance during a surgery	(b) (4)	Passed
<b>Change in laser intensity due to aging or different environmental condition</b>	To demonstrate the influence of the device ageing and degradation (like decrease in laser intensity over time or due to different environmental condition) on the performance of the device	(b) (4)	Passed
<b>Effect of surgical and ambient light on the device performance</b>	To demonstrate the influence of the surgical and ambient light on the performance of the device	(b) (4)	Passed

**SUMMARY OF CLINICAL INFORMATION**

**A. Study Design**

A clinical study was conducted to support the safety and effectiveness of the AiBiomed Parathyroid Detection System (PTeye) to aid in the identification of parathyroid (PG) tissue during thyroid and parathyroid surgical procedures.

The single blinded non-randomized study was conducted at two centers, Vanderbilt and Ohio State University Medical Center and included tissue measurements during thyroid and parathyroid surgical procedures. Measurements were taken intraoperatively by surgeons who were blinded to PTeye device output. During the surgical procedure, five thyroid data points were initially collected by touching the probe tip to the thyroid tissue. The system used these 5 points to calculate a baseline near infrared autofluorescence (NIRAF) median value and this established the reference baseline for each individual patient. If no thyroid tissue was present due to a previous thyroidectomy/thyroid ablation, baseline NIRAF median was alternatively obtained on neck muscle or trachea for that particular patient. Subsequent tissue NIRAF measurements in the patient were then

normalized to this NIRAF baseline for obtaining the detection ratio. Upon visualizing a tissue of interest, the surgeon first stated the degree of confidence in having identified tissue as parathyroid gland with high, moderate or low confidence, based solely on visual inspection of the tissue-in-situ and without relying on the PTeye device. This information was recorded for assessing the performance of the PTeye as compared to the surgeon’s visual assessment. The surgeon then placed the probe of the PTeye on the suspect tissue site and pressed the foot-pedal, resulting in tissue NIRAF intensity and detection ratio being displayed only to the study investigator and not surgeon in real-time.

The study was originally designed to compare the performance of the PTeye to a prior prototype parathyroid detection system. Of the original 133 patients enrolled, 82 patients were tested with the PTeye in its final design. There are technological differences between the PTeye and the prototype device, including ambient light interference and peak intensity to determine baseline (NIRAF), which may alter the device effectiveness results. Therefore, effectiveness results only for the PTeye final design were considered. However, for the safety results, both treatment groups are included in the summary below. Of note, there were no reported surgery or device related adverse events for the 51 patients whose results have been excluded from the final effectiveness analysis.

Subjects enrolled in the study included both men (23.5%) and women (76.5%) over the age of 18.

**Table 1: Summary of Demographic Information**

<b>Demographic Variables</b>	<b>Site A</b>	<b>Site B</b>	<b>Overall</b>
<b>Number of patients</b>	40 (38- excluding 2 patients with secondary hyperparathyroidism)	41	81 (79- excluding 2 patients with secondary hyperparathyroidism)
<b>Gender</b>			
<i>Female</i>	28 (70.0%)	34 (82.9%)	62 (76.5%)
<i>Male</i>	12 (30.0%)	7 (17.1%)	19 (23.5%)
<b>Race</b>			
<i>Caucasian</i>	34 (85.0%)	39 (95.1%)	73 (90.1%)
<i>Non-Caucasian</i>	6 (15.0%)	2 (4.9%)	8 (9.9%)
<b>Age (years)</b>	54.3 ± 15.8	52.3 ± 16.4	53.8 ± 19.9
<b>BMI (kg/m<sup>2</sup>)</b>	29.3 ± 6.2	31.6 ± 9.2	30.5 ± 7.9

**Clinical Inclusion and Exclusion Criteria**

Inclusion Criteria:

To be eligible for study enrollment, a subject was required to satisfy each of the following criteria.

1. Adults (18-99 years of age) scheduled to undergo parathyroid or thyroid surgery.

2. Willing to sign the informed written consent form.

**Exclusion Criteria:**

A subject was not eligible to participate if they met any of the following exclusion criteria.

1. Pregnant
2. Unsuitable for study participation in the opinion of the Investigator- attending surgeon.

The study was initially designed to evaluate the performance of the PTeye in differentiating between parathyroid gland and non-parathyroid gland tissue once a potential candidate tissue was surgically exposed during the procedure. This was subsequently corroborated by the surgeon’s visual identification for in situ parathyroid glands using an unvalidated confidence scale (low, medium, or high) and with histological examination for the excised parathyroid gland tissues.

**Table 2: Study Endpoints**

Primary effectiveness endpoints	Performance measured by the ability of the PTeye to accurately identify parathyroid glands [PG detection rate].
Secondary effectiveness endpoints	Intra-patient and inter-patient variability of NIRAF in thyroid and PGs.
	Effect of thyroid and PG pathology on intraoperative parathyroid Identification.
	In-vivo and ex-vivo effect of blood on NIRAF intensity of PG and thyroid with the PTeye system to assess if a hemorrhagic surgical field would affect parathyroid identification.
	Ex-vivo effect of probe-to-tissue contact pressure on PG fluorescence intensity.
Safety Endpoint	Safe use as determined by a lack of (serious) adverse events.
	The addition of no more than 5 minutes to the total procedure time during normal use of the device.

**Table 3: Subject Accountability**

	All Subjects	Final PTeye System
Enrolled subjects	N = 133	N = 82
Completed subjects	-	82
Discontinued subjects	51 (prototype device)	3
Reason for discontinuation		
Protocol deviation <sup>a</sup>		1
Previously identified disease state <sup>b</sup>		2

<sup>a</sup> Protocol deviation due to communication error between study coordinator and surgeon regarding the timing of depressing the PTeye foot pedal leading to incorrect baseline NIRAF measurements.

<sup>b</sup> Patients with secondary hyperparathyroidism were determined to exhibit irregular NIRAF in prior studies and thus, were excluded from the final effectiveness performance assessment.



The ability of the PTeye to accurately identify parathyroid glands [PG detection rate] included the following assessments using objective histology and subjective expert surgeon opinion:

### **PTeye Performance Data Analysis:**

1. **Sensitivity**- Number of true positives, (as determined by PTeye and validated by histology or surgeon's visual identification with high/moderate confidence) divided by actual positives (PG sites – total number of positives as determined by histology or surgeon's visual identification with high/moderate confidence)
2. **Specificity**: Number of true negatives, (as determined by PTeye and validated by histology or surgeon's visual identification with high/moderate confidence) divided by actual negatives (non-PG sites – total number of negatives as determined by histology or surgeon's visual identification with high/moderate confidence)
3. **PPV**: Number of true positives, (as determined by PTeye and validated by histology or surgeon's visual identification with high/moderate confidence) divided by number of device positives (total number of positives as determined by PTeye alone)
4. **NPV**: Number of true negatives, (as determined by PTeye and validated by histology or surgeon's visual identification with high/moderate confidence) divided by number of device negatives (total number of negatives as determined by PTeye alone)
5. **False positive rate**: Rate of device positive measurements when tested on actual negatives (number of negatives validated by histology or surgeon's visual identification with high/moderate confidence).
6. **False negative rate**: Rate of device negative measurements when tested on actual positives (number of positives validated by histology or surgeon's visual identification with high/moderate confidence).

Based on these parameters, overall accuracy of the PTeye in PG identification and associated kappa values were accordingly calculated.

Statistical significance of NIRAF intensities between thyroid, parathyroid gland, fat, muscle and trachea were determined using a two-tailed Student's t-test for unequal variance, with an alpha (level of significance) of 0.01. The same statistical approach was adopted to determine if there was a significant difference between NIRAF measured from normal and diseased thyroid and parathyroid glands.

### **Comparison of surgeon's visual determination versus the PTeye as validated with histology-based gold standard:**

The performance accuracy of the participant surgeons in differentiating between parathyroid gland (PG) and non-PG tissues relying on their visual skills were compared to that of the PTeye. This was performed in those cases when *in vivo* measurements were performed on tissues that were later excised for histological validation via frozen section or Hematoxylin-Eosin stained tissue section analysis by the pathologists that could serve as the gold standard. Due to lack of histological validation of in-situ tissues, these were not considered for comparing performance accuracy between the surgeons and the PTeye. In addition, comparison of surgeon versus PTeye

were evaluated for each investigational site/study center. All participant surgeons at both centers were high-volume surgeons (who perform >25 thyroid surgeries per year and >15 parathyroid surgeries per year).

### **Assessing variability and associated factors within patient data acquired with the PTeye:**

Following data acquisition and analysis, the report also investigated: (i) the distribution of demographic variables at both study centers including: age (18- 99 years of age), gender (male or female), race (Caucasian or non-Caucasian), body-mass index (BMI) at time of surgery, (ii) Intra-patient and inter-patient variability of NIRAF in thyroid and PGs respectively and (iii) the effect of thyroid and parathyroid disease on intraoperative PG identification.

### **Influence of blood on NIRAF of thyroid and PG:**

#### **A. Ex vivo Validation:**

The effect of blood on the NIRAF intensity of PG and thyroid was assessed *ex vivo* with the PTeye in order to determine if a hemorrhagic surgical field would affect PG identification. Three fresh frozen specimens each, of normal thyroid and PG adenoma were obtained from the NIH funded Co-operative Human Tissue Network (Vanderbilt University Medical Center, Nashville, TN). After thawing the specimens, at least six NIRAF measurements were obtained from each specimen *ex vivo*. To simulate a hemorrhagic surgical field, 0.5 cc of heparinized murine blood was introduced on to the specimen surface. NIRAF intensity of each specimen was measured with the PTeye and normalized to the thyroid NIRAF and grouped into four categories: (i) thyroid without blood (n, (ii) thyroid with blood, (iii) PG without blood and (iv) PG with blood, with each group consisting of 18 NIRAF measurements. Statistical significance was determined using a two-tailed Student's t-test for unequal variance, with an alpha level of significance, alpha of 0.01.

#### **B. In vivo validation:**

The influence of a hemorrhagic surgical field on PG identification with the PTeye was also tested *in vivo* using 4 PGs from 3 patients. The surgeon upon identifying a tissue thought to be the PG with high/moderate confidence, obtained PTeye measurement from the tissue. In these three patients –1-2 measurements were taken when the PG was covered with blood, which routinely occurs during the surgical procedure. After the measurement, the surgeon suctioned the blood away, rinsed the tissue with saline and repeated the PTeye measurement on the same tissue site. Detection ratios were grouped for three categories: (i) thyroid, (ii) PG with blood and (iii) PG without blood, with each group consisting of at least 6 NIRAF measurements. Statistical significance between (i) thyroid and PG without blood and (ii) thyroid and PG with blood were determined by a 2-tailed Student's t-test for unequal variance, with an alpha level of significance of 0.01.

### **Effect of probe-to-tissue contact pressure on tissue NIRAF measurements with the PTeye:**

The effect of probe-to-tissue contact pressure on tissue NIRAF intensity was examined *in vitro* on excised fresh frozen human PG (n=3) and thyroid (n=2) tissues. NIRAF measurements with the PTeye were collected where the user reported the probe contact pressures qualitatively to be 'mild', 'moderate', and 'high'. Differences in PG detection ratios were correlated with the degree of probe-to-tissue contact pressure.

### **Schedule of assessments:**

There were no formal follow-up assessments or visits for the patient: subjects exit the study at the conclusion of standard recovery from the surgical procedure.

### **Safety definitions and reporting requirements:**

All adverse events (AEs), regardless of seriousness, severity, or relationship to the study device, were to be recorded in the Case Report Forms (CRF) by the investigators and/or study coordinators and reported to corresponding IRBs at the two centers and to the Principal Investigator. The evaluation was to include a determination of the seriousness and severity of the event, whether the event or the severity of the event was anticipated or unanticipated, and the relationship of the event to the study device.

A serious adverse event (SAE) is defined according to ISO 14155:2003 as any adverse event that:

- Led to a death
- Led to a serious deterioration in the health of the subject that
- Resulted in a life-threatening illness or injury
- Resulted in a permanent impairment of a body structure or a body function
- Required in-patient hospitalization or prolongation of existing hospitalization
- Resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function

An unanticipated adverse device effect (UADE) is defined per 21 CFR 812.3 as any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

SAE and UADE were to be reported by the investigators to the IRB and to AiBiomed within 24 hours. Serious AEs and UADEs were documented on the Serious Adverse Event Form.

## **Safety and Effectiveness Results**

### **1. Safety Results**

At the end of patient follow-up period of two weeks, no adverse events related to the procedure or during the study period were reported. There were no adverse events, SAE's, or UADE's reported in the 81 patients considered for effectiveness data analysis. No clinical issues or adverse events related to the intra-operative use of the device description of procedural difficulties, or device complaints were reported at the closure of the study.

Individual measurements once the PTeye device is set up take approximately 2 seconds. (5) thyroid baseline measurements, (4) extra thyroid measurements, (8) PG measurements, (2) fat measurements, (2) trachea measurements, and (2) muscle measurements per patients took approximately one minute of additional total procedure time during normal use of the device, this was under the 5-minute pre-defined cut-off.

## 2. Effectiveness Results

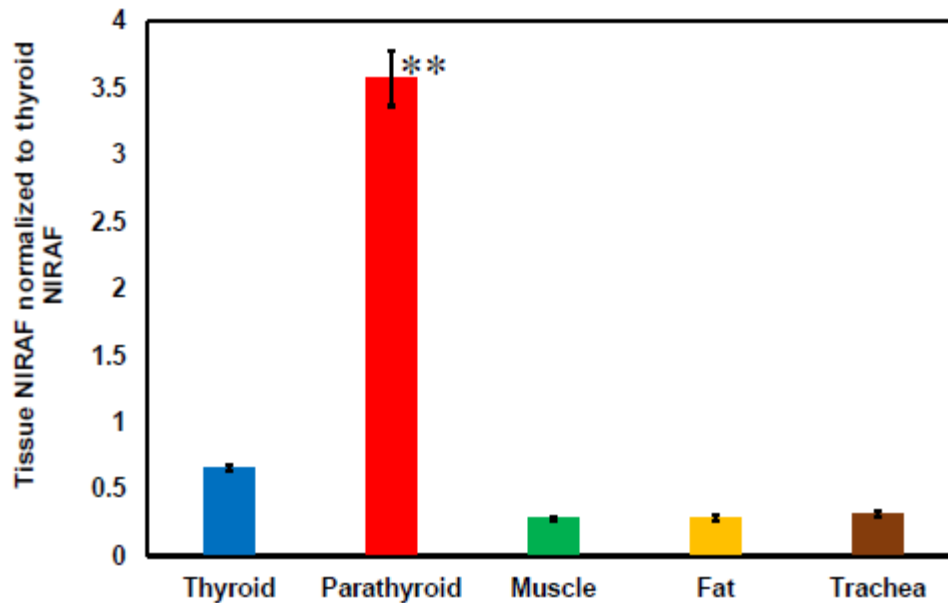
### **Primary endpoint parathyroid identification rate:**

Measurements were obtained using the final design of the PTeye on 181 PGs and 546 non-PG tissues (194 thyroid, 116 fat, 119 neck muscle, and 117 trachea) in 81 patients. Individual performance data was populated for all 81 patients (40 from site A and 41 from site B). Of the 181 PGs measured, fluorescence measurements of 68 PGs (68/181, 37.6%) were confirmed with histology. The remaining 113 PGs could not be confirmed with histology and were validated based on high or medium confidence of the surgeon's visual assessment. Tissues identified with low confidence by the surgeon were excluded from further analysis unless histological validation was obtained from those tissues.

#### **A. Normalized NIRAF Intensity:**

Testing with the PTeye system yielded 362 measurements from 181 PGs and 546 measurements from non-PG locations in 81 patients undergoing parathyroidectomy and/or thyroidectomy.

### **Figure 1: Normalized NIRAF Intensity to Tissues:**



**NIRAF measured with the PTeye on different neck tissues normalized to NIRAF of the thyroid. Error bar – Standard Error. \*\*p-value <0.01 for normalized NIRAF of PGs compared to the non-PG tissues – thyroid, fat, muscle and trachea.**

As seen above, normalized NIRAF intensity measured from PGs was significantly higher than that of the non-PG tissues in the neck such as thyroid, fat, muscle and trachea (p-value =  $1.21 \times 10^{-41}$ ). Overall, the normalized NIRAF intensity for PG tissue measured with the PTeye was about 5.4 times higher than that of the measured thyroid, while muscle, fat and trachea showed little to no NIRAF intensity.

**B. Accuracy of PG identification based on histology/surgeon validation:**

The PTeye could successfully identify PGs with 92.3% sensitivity (167/181) and 97.3% specificity (531/546). PG identification with the PTeye system had an overall accuracy of 96% (kappa = 0.89) with 2.7% false positive rate and 7.7% false negative rate. The PPV and NPV for this system were 91.8% and 97.4% respectively. The performance accuracy of PTeye in identifying PG tissue was achieved without needing to switch off ambient OR lights. Corresponding information from the surgeon assessment and histology (when available) from the same tissue in the same patient is presented below.

**Table 4: PTeye Performance Based on Histology and Expert Surgeon Corroboration**

<b>All Diagnoses (with histology)</b>	Histology+ for Parathyroid	Histology- for Parathyroid
PTeye+ for Parathyroid	61	1
PTeye- for Parathyroid	7	4
<b>All Diagnoses (with surgeon's eye)</b>	Expert Surgeon+ for Parathyroid	Expert Surgeon- for Parathyroid
PTeye+ for Parathyroid	106	14
PTeye- for Parathyroid	7	527
<b>All Diagnoses (combined)</b>	Gold Standard+ for Parathyroid	Gold Standard- for Parathyroid
PTeye+ for Parathyroid	167	15
PTeye- for Parathyroid	14	531

**Parathyroid glands (with histological validation):**

Accuracy: 89.0%; Kappa: 0.45;  
Sensitivity: 89.7%; Specificity: 80.0%;  
PPV: 98.4%; NPV: 36.4%;  
False Positive Rate: 20.0%; False Negative Rate: 11.3%

**Parathyroid glands (with surgeon's eye for validation):**

Accuracy: 96.8%; k: 0.89;  
Sensitivity: 93.8%; Specificity: 97.4%;  
PPV: 88.3%; NPV: 98.7%;  
False Positive Rate: 2.6%; False Negative Rate: 6.2%

**Overall Performance**

Accuracy: 96.0%; Kappa: 0.89;  
Sensitivity: 92.3%; Specificity: 97.3%;  
PPV: 91.8%; NPV: 97.4%;  
False Positive Rate: 2.7%; False Negative Rate: 7.7%

**Histology and surgeon's assessment information that validates PTeye performance in differentiating between PG and non-PG tissues in 81 patients at sites A & B – including 2 r-SHP patients. Gold standard indicates histological assessment for excised tissues and surgeon's visual assessment with high-moderate degree of confidence for in-situ tissues**

The performance of the PTeye improves further upon exclusion of renal-induced secondary hyperparathyroidism (r-SHPT) patients, in whom the PGs exhibit NIRAF very irregularly as found in prior studies by McWade *et al.* Surgery (2016). Based on McWade *et al.* results, the labeling excludes using the PTeye in patients with r-SHPT. Removing data from the r-SHPT patients, led to the PTeye identifying PGs with an even higher sensitivity at 93.6% (162/173), while a 97.1% specificity (510/525) was obtained. As a result, an overall accuracy of 96.3% (kappa = 0.90) was achieved with 2.9% false positive rate and 6.4% false negative rate. The PPV and NPV for this system were 91.5% and 97.9% respectively.

**Table 5: PTeye Performance Based on Histology and Expert Surgeon Corroboration (excluding secondary hyperparathyroid patients)**

<b>All Diagnoses (with histology)</b>	Histology+ for Parathyroid	Histology- for Parathyroid
PTeye+ for Parathyroid	56	1
PTeye- for Parathyroid	4	4
<b>All Diagnoses (with surgeon's eye)</b>	Expert Surgeon+ for Parathyroid	Expert Surgeon- for Parathyroid
PTeye+ for Parathyroid	106	14
PTeye- for Parathyroid	7	506
<b>All Diagnoses (combined)</b>	Gold Standard+ for Parathyroid	Gold Standard- for Parathyroid
PTeye+ for Parathyroid	162	15
PTeye- for Parathyroid	11	510

**Parathyroid glands (with histological validation):**  
Accuracy: 92.3%; Kappa: 0.58;  
Sensitivity: 93.3%; Specificity: 80.0%;  
PPV: 98.3%; NPV: 50.0%;  
False Positive Rate: 20.0%; False Negative Rate: 6.7%

**Parathyroid glands (with surgeon's eye for validation):**  
Accuracy: 96.7%; k: 0.89;  
Sensitivity: 93.8%; Specificity: 97.3%;  
PPV: 88.3%; NPV: 98.6%;  
False Positive Rate: 2.7%; False Negative Rate: 6.2%

**Overall Performance:**  
Accuracy: 96.3%; Kappa: 0.90;  
Sensitivity: 93.6%; Specificity: 97.1%;  
PPV: 91.5%; NPV: 97.9%;  
False Positive Rate: 2.9%; False Negative Rate: 6.4%

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**Histology and surgeon's assessment information that validates PTeye performance in differentiating between PG and non-PG tissues in 79 patients at sites A & B – excluding 2 r-SHP patients.**

**C. Performance of the surgeon's eye versus the PTeye System when correlated with histological validation**

The four surgeons at the two study sites are high- volume surgeons who perform more than 25 thyroidectomies and more than 15 parathyroidectomies each year. At study site A (**Vanderbilt**), surgeon #1 has 16 years of experience as a practicing endocrine surgeon while surgeon #2 has 4 years of the same. Similarly, at study site B (**Ohio State**), surgeon #3 and surgeon #4 have 16 and 4 years respectively of experience as endocrine surgeons.

At site A, the surgeons could correctly identify 95.2% of the excised PGs (40 out of 42) in comparison to 92.9% detected with the PTeye (39 out of 42), when cross validated with histology. In contrast, the PTeye performed better at site B by correctly detecting 94.4% of the excised PGs (17 out of 18), in comparison to 88.9% detected by the surgeons (16 out of 18). Overall the detection rate for PG tissues when validated with histology remained the same for surgeons versus the PTeye at 93.3% as seen below. The PTeye however, outperformed the surgeons at both study sites in correctly identifying non-PG tissues which were excised for histological validation. The PTeye was accurate in determining that the

tissue was not a PG in 80% of the specimens (4 out of 5), while the surgeons were incorrect for all the non-PG specimens (0 out of 5).

**Table 6: Performance of the surgeons versus that of the PTeye when validated with histology for excised PGs – excluding data from 2 r-SHPT patients**

Diagnoses (with histology)	Excised PGs			Excised non-PGs tissue (excised assumed as PG)*		
	Surgeons	PTeye	Histology	Surgeons	PTeye	Histology
Site A	40	39	42	0	3	4
Percentage	40/42 (95.2%)	39/42 (92.8%)		0/4 (0.0%)	3/4 (75.0%)	
Site B	16	17	18	0	1	1
Percentage	16/18 (88.9%)	17/18 (94.4%)		0/1 (0.0%)	1/1 (100.0%)	
Site A + Site B	56	56	60	0	15	5
Percentage	56/60 (93.3%)	56/60 (93.3%)		0/5 (0.0%)	4/5 (80.0%)	

**Table 7: Individual surgeon contribution to the number of surgeries and tissue readings**

Surgeon with experience. (16 or 4 years)	Site A. Vanderbilt B. Ohio State	Number of surgeries	Number of PG's	Number of PG readings	Number of non PG readings
Surgeon A Experience: 16 years	Vanderbilt University Medical Center	22	64	128	97
Surgeon B Experience: 4 years	Vanderbilt University Medical Center	18	48	96	119
Surgeon C Experience: 16 years	Ohio State University Medical Center	38	63	126	305
Surgeon D Experience: 4 years	Ohio State University Medical Center	3	6	12	25
<b>Total</b>		<b>81</b>	<b>181</b>	<b>362</b>	<b>546</b>

**Secondary Effectiveness Endpoints:**

**A. Intra-patient and inter-patient variability of NIRAF in PG and thyroid tissues:**

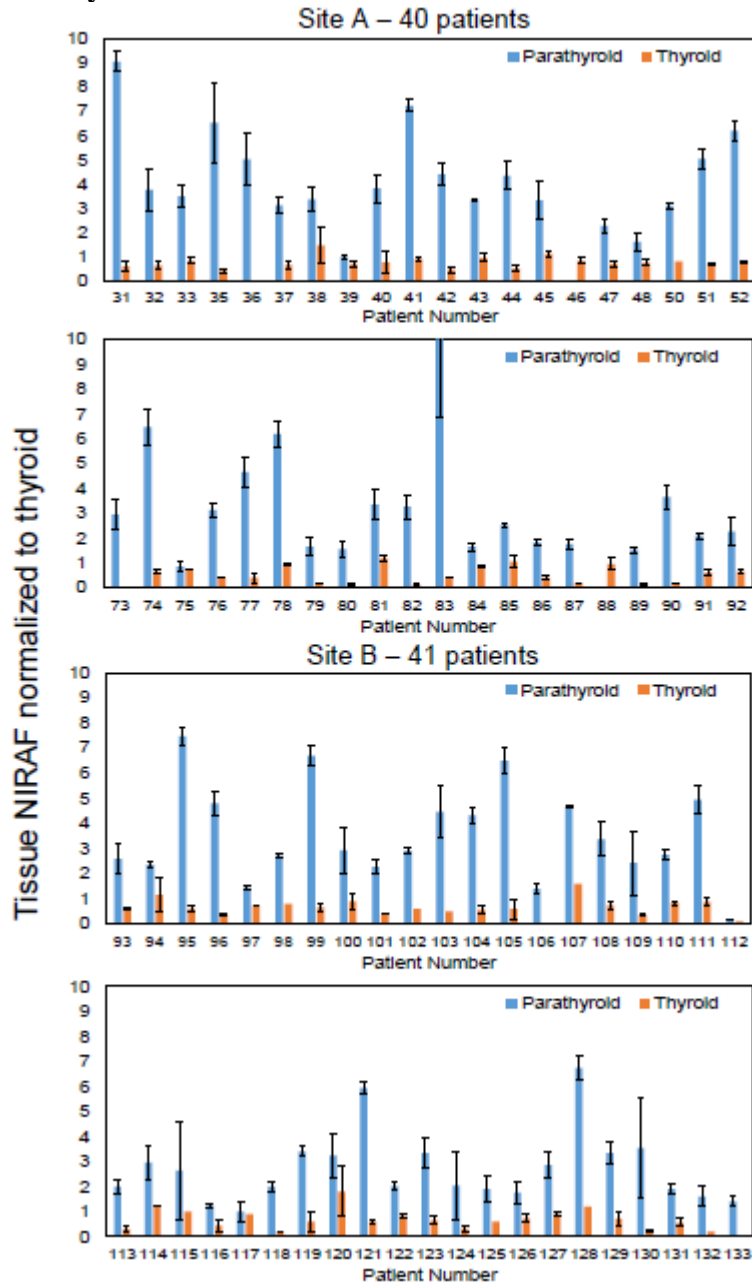
Among the 81 patients studied with the PTeye, no PG tissues were visually identified by the surgeon in Patient #46 and #88 for the purpose of device testing. There were no thyroid NIRAF measurements in patient #36, #106 and #133, as these patients had no thyroid remnants due to previous thyroid interventions. Baseline NIRAF was performed on muscle



or trachea in these patients. While the baseline thyroid NIRAF was obtained for patient #73, additional thyroid measurements were not obtained due to lack of time.

Data analysis of the NIRAF from PG and thyroid tissues across these patients revealed that intra-patient variability of normalized NIRAF in thyroid averaged at 28.6%, while that of the PGs was 34%. When the inter-patient variability was analyzed as the deviation of individual patient NIRAF from the mean calculated across all patients expressed as a percentage, the inter-patient variability for normalized NIRAF in thyroid averaged at 74%. In comparison, the mean inter-patient variability for normalized NIRAF in PGs was about 1.5 times higher at 112%. Despite the higher intra-patient and inter-patient variability, normalized NIRAF intensities for PGs were consistently higher than that of the thyroid glands. It can also be noted that PG NIRAF are notably lower compared to the thyroid in the two r-SHPT subjects, i.e. patient #39 and #48 – as seen in the figure below.

**Figure 2: Intra-patient and inter-patient variability of tissue NIRAF measured with the PTeye in PG and thyroid tissues**



**Intra-patient and inter-patient variability of tissue NIRAF measured with the PTeye in PG and thyroid tissues. Since tissue NIRAF normalized to thyroid NIRAF for PGs in Patient #83 had values that exceeded 30, the y-axis was truncated at an upper limit of 10 to depict intra-patient and inter-patient variability in tissue NIRAF among all 81 patients. Error bars – Standard error**

Since tissue NIRAF normalized to thyroid NIRAF for PGs in Patient #83 had values that exceeded 30, the y-axis was truncated at an upper limit of 10 to depict intra-patient and inter-patient variability in tissue NIRAF among all 81 patients. Error bars – Standard error

**B. Effect of thyroid and/or PG disease on NIRAF intensity assessed by the PTeye:**

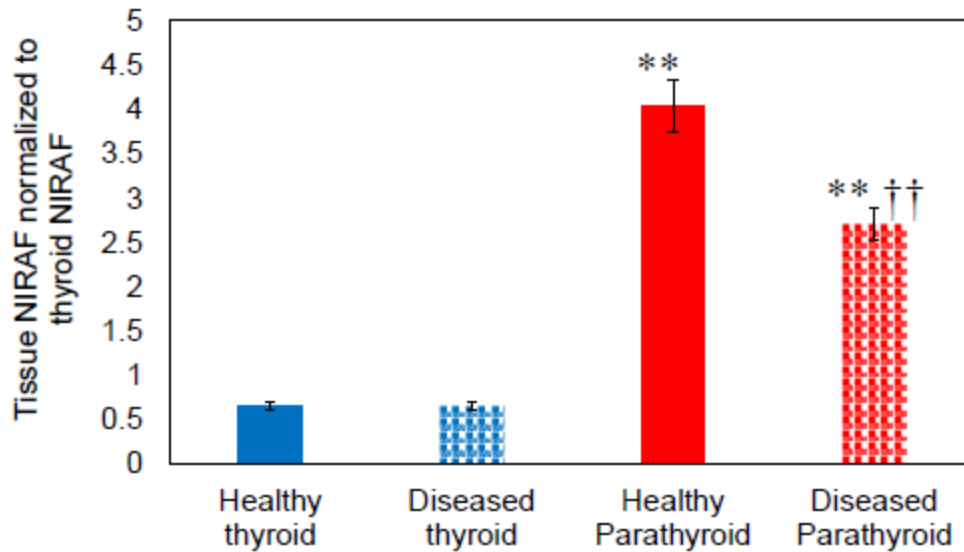
As shown below, patients assessed with the PTeye system included: (i) 46 cases of diseased thyroid with normal PG, (ii) 31 cases of diseased PG with normal thyroid, (iii) 3 cases of diseased thyroid *and* diseased PG and (iv) 1 case of normal thyroid *and* PG (admitted for prophylactic thyroidectomy). The diseased thyroid cases comprised of (i) non-toxic benign thyroid diseases (n=23), (ii) toxic benign thyroid diseases (n=8) and malignant thyroid conditions (n=15). Cases of diseased PGs were predominantly primary hyperparathyroidism (n=28), with two renal failure induced-secondary hyperparathyroidism (r-SHPT) and one tertiary hyperparathyroidism cases, (note that the occurrence of the latter two diseases are very rare). PG rate was found to be the lowest for renal failure induced secondary hyperparathyroidism (r-SHPT) patients at 62.5%. Therefore r-SHPT patients were excluded from the indications for use of the PTeye.

**Table 8: Distribution of different disease groups tested with PTeye and PG identification rate for each disease group.**

<b>Thyroid/Parathyroid disease</b>	<b>Site A (# of Patients)</b>	<b>Site B (# of Patients)</b>	<b>Total (# of patients)</b>	<b>Parathyroid gland identification rate # of PG glands, (% identified)</b>
Benign thyroid disease-non-toxic (solitary nodule/multinodular goiter/Hashimoto's thyroiditis)	12	11	23	35/40 (87.5%)
Benign thyroid disease-toxic (Grave's Disease/solitary nodule/multinodular goiter/thyroiditis)	2	6	8	17/18 (94.4%)
Malignant thyroid disease	6	9	15	38/39 (97.4%)
Primary hyperparathyroidism	16	12	28	61/65 (93.9%)
Secondary hyperparathyroidism	2	0	2	5/8 (62.5%)
Tertiary hyperparathyroidism	1	0	1	3/3 (100.0%)
Concomitant thyroid-parathyroid disease	0	3	3	5/5 (100.0%)
Prophylactic thyroidectomy for MEN2A	1	0	1	3/3 (100.0%)

As observed in the figure below, there was no significant difference seen in the normalized NIRAF intensity between healthy and diseased thyroid glands ( $p=0.96$ ). On the other hand, diseased PGs exhibited a lower normalized NIRAF intensity as compared to healthy PGs with demonstrable statistical significance ( $p=0.00012$ ). However, PG tissue exhibited significantly higher normalized NIRAF intensity as compared to the thyroid gland, irrespective of whether the thyroid or PG was normal or diseased ( $p < 0.00001$ )

**Figure 3: Variation of normalized NIRAF intensity between healthy thyroid, diseased thyroid, healthy PG and diseased PG states tested with the PTeye**



**Variation of normalized NIRAF intensity between healthy thyroid, diseased thyroid, healthy PG and diseased PG states tested with the PTeye. Error bar – Standard Error. \*\*p-value <0.001 for normalized NIRAF of PG compared to thyroid – regardless of whether healthy or diseased, ††p-value <0.001 for normalized NIRAF of healthy PG compared to diseased PG.**

Performance of the PTeye in Cases of Renal Failure Induced Secondary Hyperparathyroidism (r-SHPT)

Normalized NIRAF intensity of the PGs in r-SHPT patients were frequently found to be lower than 1.2 (the threshold set for PG identification), in contrast with healthy and other types of diseased PGs. In the 2 r-SHPT patients evaluated with the PTeye, only 62.5% of the PGs (5 out of 8) had a normalized NIRAF intensity greater or equal to 1.2. This was also in agreement with the findings reported in an earlier study reported by McWade et al. (Surgery, 2016). Sensitivity of PG identification with the PTeye improved to 93.6% (162/173 PGs), if patients with r-SHPT were excluded from performance analysis. The finding suggests that a device such as PTeye in its present design may not be useful in aiding PG identification in r-SHPT cases.

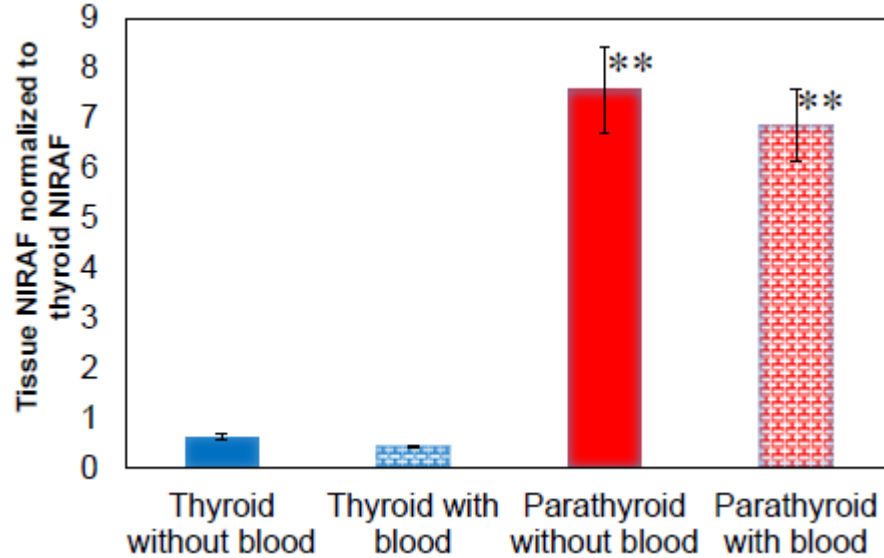
**C. Influence of hemorrhagic field on tissue NIRAF measurements with the PTeye:**

*Effect of Blood on NIRAF on thyroid and PG specimen's ex vivo*

The influence of blood on intraoperative PG identification with PTeye was studied with an *ex vivo* simulated experiment using thyroid and PG specimens covered with heparinized murine blood. **Figure 12** represents data from an *ex vivo* experiment that shows the effect of blood on NIRAF measured from thyroid and/or PG tissues using the PTeye. The findings indicate that normalized NIRAF intensity of thyroid tissue was lower in the presence of blood as compared to that of the same thyroid specimens when blood was washed away (p = 0.007). In comparison, normalized NIRAF of PG specimens with blood was lower than that of PG specimens without blood but not statistically significantly (p=0.53). Moreover, the PG specimens was found to have normalized

NIRAF intensity significantly higher than the thyroid with and without blood – regardless of the presence of blood on the PG itself.

**Figure 4: Influence of blood on normalized NIRAF intensity ex vivo**

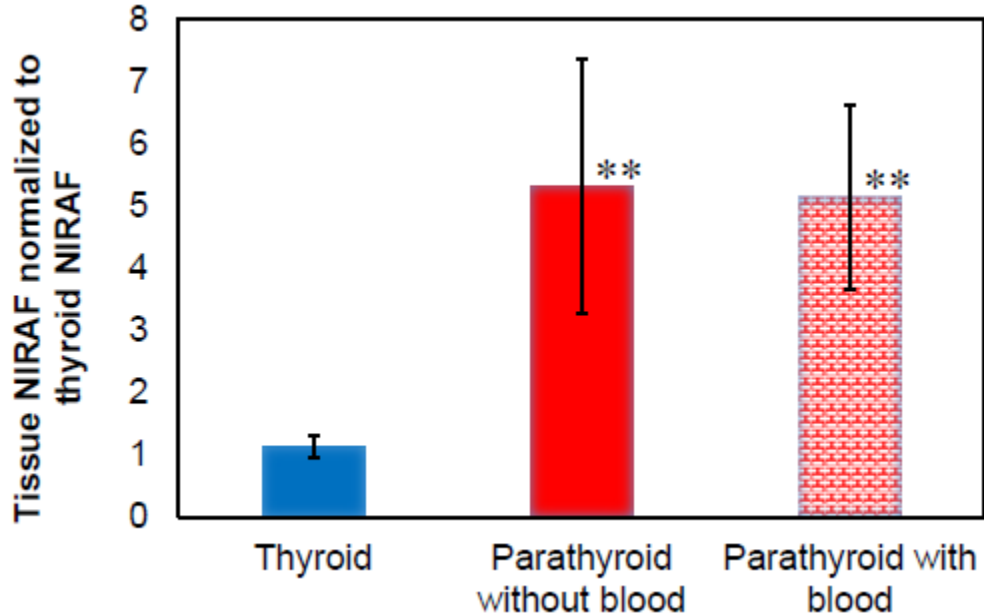


**Influence of blood on normalized NIRAF intensity measured ex vivo on 3 human PG and thyroid specimens each with the PTeye (6 measurements each with and without blood). Error bar – Standard Error. \*\*\*p-value <0.01 for NIRAF intensity of PG compared to thyroid.**

*Effect of Blood on NIRAF on thyroid and PG specimens in vivo*

The same findings were observed upon investigating the influence of blood *in vivo* as observed in the figure below. Based on the normalized NIRAF measurements obtained from three (3) patients with two measurements per PG (with and without blood), there is no significant difference in the NIRAF of PGs in presence and absence of blood even in an *in vivo* setting ( $p=0.95$ ). Further, the PGs *in vivo* were found to have normalized NIRAF intensity significantly higher than the thyroid, regardless of the presence of blood on the PG ( $p=0.005$ ).

Figure 5: Influence of blood on normalized NIRAF intensity in vivo

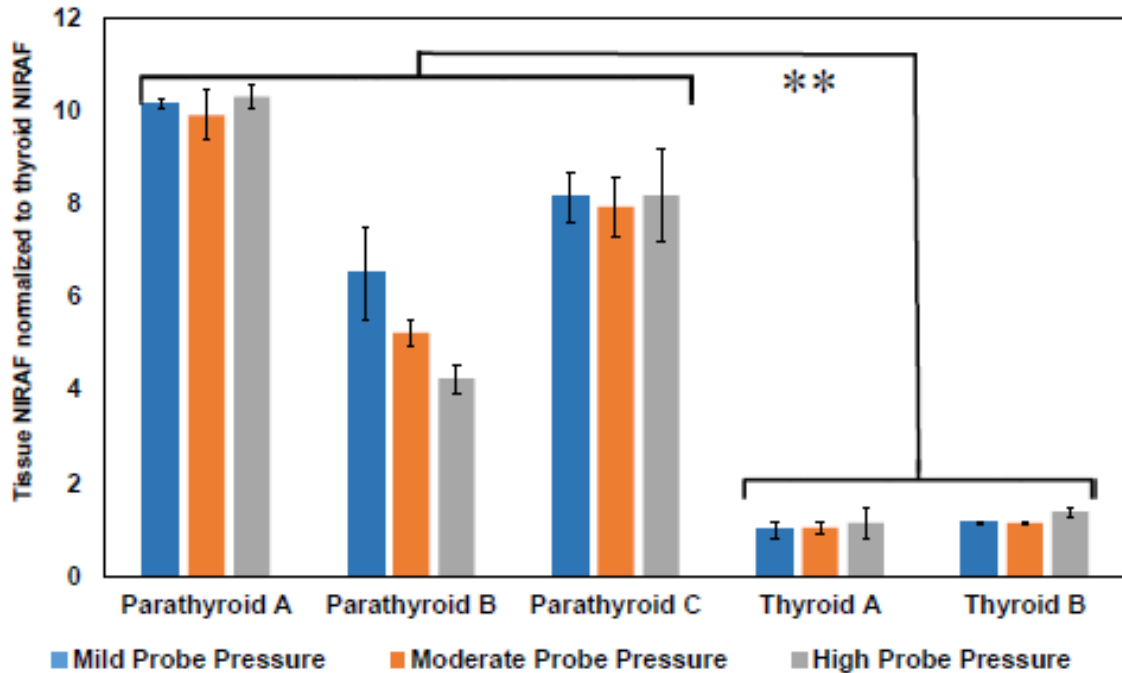


Influence of blood on normalized NIRAF intensity measured *in vivo* on PGs in 3 patients with the PTeye (2 measurements per parathyroid without and with blood). Error bar – Standard Error. \*\* denotes statistical significance between blue and red bar, with p-value <0.01 for NIRAF intensity of PG compared to thyroid.

**D. Effect of probe-to-tissue contact pressure on NIRAF measurements with the PTeye:**

Upon assessing the influence of probe contact pressure on tissue NIRAF measurement with the PTeye, no notable difference in the tissue NIRAF measurements was observed with probe pressure (mild, moderate or high). This applied to both PG as well as thyroid specimens as seen in the figure below. It was also noted that PG NIRAF levels stayed consistently and significantly higher than that of the thyroid, regardless of the probe contact pressure for either tissue type ( $p=2.2 \times 10^{-10}$ )

**Figure 6: Influence of probe pressure on normalized NIRAF intensity measured *ex vivo***



**Influence of probe pressure on normalized NIRAF intensity measured *ex vivo* on thawed frozen human PG and thyroid specimens with the PTeye. Error bar – Standard Error. \*\*p-value <0.001 for NIRAF intensity of PG compared to thyroid.**

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

**LABELING**

The device user manual and instructions for use include a description of the device technical parameters and instructions for use for the device. The user manual also contains relevant findings from the clinical study with the detection performance characteristics of the device when used as intended. The document also states the shelf life for any sterile components as well as the necessary measures to properly dispose of any single use items and clean the reusable components of the device.

The user manual includes a warning for use with patients with secondary hyperparathyroidism or parathyroid cysts. Additionally, there is a warning not to use the PTeye device as a parathyroid tissue locator. Lastly, there is a precaution stating that due to a small sample size, limited clinical data is available regarding the safety and effectiveness of the PTeye System for rare disease states such as: tertiary hyperparathyroidism, concomitant thyroid-parathyroid diseases, malignant parathyroid diseases, or other circumstances when prophylactic thyroidectomies are performed in individuals at high-risk for certain diseases such as MEN2A.

Labeling for this device is in accordance with the special controls listed below.

**RISKS TO HEALTH**

The table below identifies the risks to health that may be associated with use of the autofluorescence detection device for general surgery and dermatological use and the measures necessary to mitigate these risks.

Table 9 – Identified Risks to Health and Mitigation Measures

<b>Identified Risks to Health</b>	<b>Mitigation Measures</b>
Electrical, mechanical, or thermal hazards leading to user injury or discomfort	Electromagnetic compatibility testing Electrical, mechanical and thermal safety testing Software verification, validation, and hazard analysis Labeling
Tissue, skin burn, or eye injury due to light and laser exposure	Light and laser exposure safety testing Labeling
Infection and cross contamination	Sterilization validation Shelf life testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
False identification of target tissues or structures leading to errors in patient management (e.g., removal of healthy tissue or not removing diseased tissue)	In vivo performance testing Software verification, validation, and hazard analysis Labeling



## **SPECIAL CONTROLS:**

In combination with the general controls of the FD&C Act, the autofluorescence detection device for general surgery and dermatological use is subject to the following special controls:

- (1) In vivo testing under the anticipated conditions of use must characterize the ability of the device to detect autofluorescent signals from tissues or structures consistent with the indications for use.
- (2) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (3) Performance testing must demonstrate the electromagnetic compatibility and electrical, mechanical and thermal safety of the device.
- (4) Software verification, validation, and hazard analysis must be performed.
- (5) Performance testing must demonstrate the sterility of patient-contacting components of the device.
- (6) Performance testing must support the shelf life of device components provided sterile by demonstrating continued sterility and package integrity over the labeled shelf life.
- (7) Performance testing must demonstrate laser and light safety for eye, tissue and skin.
- (8) Labeling must include the following:
  - (i) Instructions for use;
  - (ii) The detection performance characteristics of the device when used as intended; and
  - (iii) A shelf life for any sterile components.

## **BENEFIT/RISK DETERMINATION**

### **Risks:**

The risks of the device are based on nonclinical laboratory studies as well as data collected in a clinical study described above.

No device or procedure related adverse events (AEs), serious adverse events (SAEs), or unanticipated adverse device effects (UADEs) were observed in the clinical study. This is likely due to limitations of the pivotal study design. Not all end users (non-endocrine surgeon-specialists) were tested and no additional human factors testing was performed. Due to the single blinded study design (surgeons blinded to device output) we do not know if device use aided in the identification of parathyroid tissue (e.g. surgeon left tissue behind that was healthy parathyroid tissue or removed uncertain tissue due to device identification/confirmation as parathyroid tissue). The study demonstrated the risks surgeons and patients would have using current techniques of: visual identification of parathyroid gland tissue, intra-operative parathyroid hormone measurement, and frozen histology. The pivotal clinical study was a comparative study to determine the sensitivity/specificity/accuracy of the subject device in identifying parathyroid tissue compared to expert surgeon opinion and histology. Given the clinical study design limitations, there is a moderate degree of uncertainty for the risks of device use. The potential risks of incorrect parathyroid gland identification during parathyroid and thyroid surgery are well-known, namely:

- Accidental removal of parathyroid tissue during surgical procedures (4-20%)

- Accidental injury to parathyroid tissue during surgical procedures
- Hypocalcemia(hypoparathyroidism) after thyroid/parathyroid surgery (20-30%)
- Increased operative time due to prolonged identification/confirmation of parathyroid glands (use of frozen histology or PTH blood testing)

The degree to which these risks will be experienced by both end user and patient using the PTeye device is uncertain given the moderate degree of risk uncertainty due to the lack of supportive data due to the study design.

Benefits:

The probable benefits of the device are based on nonclinical laboratory studies as well as data collected in a clinical study described above.

The magnitude of the clinical benefit has been not established based on the study design and data provided by the sponsor. There is potential for clinical benefit due to device use, namely:

- Prevent accidental removal of parathyroid tissue during surgical procedures (4-20%)
- Prevent accidental injury to parathyroid tissue during surgical procedures
- Reduce the risk of hypocalcemia (hypoparathyroidism) after thyroid/parathyroid surgery (20-30%)
- Reduce Operative time with positive identification of parathyroid (no or reduced frozen or PTH blood testing)

The pivotal study represents a comparative study, there is a lack of pre-specified: endpoints and success criteria. Robustness of the data is moderate due to the single blinded study design and quantitative histological confirmation of tissues in the pivotal study. The ability to accurately identify parathyroid tissue using the subject device, PTeye, has been established from the pivotal study data. The methods to confirm device ability in detecting parathyroid tissue are a combination of an unvalidated, subjective, four endocrine expert surgeons' opinion/confidence scale (low, medium, and high) in correctly identifying parathyroid tissue and histology confirmed specimens in 37.6% (68/181) of the parathyroid measurements (81 patients, 181 parathyroid gland measurements) used to determine true positive and true negative tissue identification rates.

The usability of the device to detect parathyroid tissue is limited to the testing of expert endocrine surgeons. The device is indicated for use only once a probable parathyroid is visualized by a surgeon seeking confirmation (identification aide) and should not be applied for localizing a 'missing' parathyroid (i.e. not to be used as a parathyroid finder or locator). A surgeon not familiar with identifying parathyroid tissue may not benefit from device use and this is compounded by the study design limited to expert endocrine surgeon testing to support parathyroid identification rates of the device itself. If the surgeon (end-user) does not benefit from device use, the patient will not benefit from device use (lower operative time, reduce parathyroid injury or accidental removal rates, reduce post-operative hypocalcemia rates). The data does support the feasibility of device use to identify parathyroid tissue as well as an expert surgeon 93.3% in most disease states (not including secondary hyperparathyroidism) and has potential for clinical benefit (for both surgeon and patient alike).

Risks of device use, and study limitations are mitigated with warnings for use in patients with: secondary hyperparathyroidism, parathyroid cysts, or for using the PTeye device to locate parathyroid tissue instead of as an adjunctive aid in parathyroid identification of visually confirmed parathyroid tissue. Additionally, device use risks and study design limitations are further mitigated with the addition of a precaution stating that “Due to a small sample size, limited clinical data is available regarding the safety and effectiveness of the PTeye System for rare disease states such as: tertiary hyperparathyroidism, concomitant thyroid-parathyroid diseases, malignant parathyroid diseases, or other circumstances when prophylactic thyroidectomies are performed in individuals at high-risk for certain diseases such as MEN2A.”

Lastly, the risks of device use can be mitigated so that the benefits outweigh the risks. The risks of device use have not been fully established or understood from the limited testing design and human factors provided in the submission. However, the moderate uncertainty risk level can be mitigated if using the subject device as an adjunct to current techniques of parathyroid identification (visual inspection, frozen section histology, and intra-operative parathyroid blood level measurements). Adjunctive medical devices are defined as: Therapeutic or diagnostic products used in conjunction with but not required by another medical assessment or intervention and not intended to be a sole therapy or stand-alone diagnostic. Using the PTeye device as an adjunct diagnostic device in conjunction with current techniques may offer potential clinical benefit to the end-user and patient while mitigating device use risks to levels already experienced by patients undergoing thyroid or parathyroid surgery.

### Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

### Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

The AiBiomed Parathyroid Detection System (Model PTeye) is an adjunctive tool intended to aid in the identification of parathyroid tissue by confirming parathyroid tissue already visually located by the surgeon.

The probable benefits outweigh the probable risks for the Parathyroid Detection System (PTeye). The device provides benefits and the risks that can be mitigated using general controls and the identified special controls.

## **CONCLUSION**

The De Novo request for the Parathyroid Detection System (PTeye) is granted and the device is classified under the following:

Product Code: QDF

Device Type: Autofluorescence detection device for general surgery and dermatological use

Class: II

Regulation: 21 CFR 878.4550

## **REFERENCES**

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