November 2, 2018

AiBiomed, Corp.
% Al Memmolo
Convergent Clinical, Inc.
6648 Surf Crest St.
Carlsbad, California 92011

Re: DEN170056
Trade/Device Name: Parathyroid Detection (Model PTeye) System
Regulation Number: 21 CFR 878.4550
Regulation Name: Autofluorescence detection device for general surgery and dermatological use
Regulatory Class: Class II
Product Code: QDF
Dated: September 26, 2017
Received: September 27, 2017

Dear Al Memmolo:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Parathyroid Detection (Model PTeye) System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Parathyroid Detection (Model PTeye) System, and substantially equivalent devices of this generic type, into Class II under the generic name autofluorescence detection device for general surgery and dermatological use.

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On

December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On September 25, 2017, FDA received your De Novo requesting classification of the Parathyroid Detection (Model PTeye) System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Parathyroid Detection (Model PTeye) System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request and responses to the additional information requests, FDA has determined that, for the previously stated indications for use, the Parathyroid Detection (Model PTeye) System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	**Mitigation Measures**
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

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 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.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the autofluorescence detection device for general surgery and dermatological use they intend to market prior to marketing the device.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and

Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Jessica Mavadia-Shukla at 301-348-1596.

Sincerely,

Angela C. Krueger -S

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health