DE NOVO CLASSIFICATION REQUEST FOR OSTEOPROBE

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Bone indentation device. A bone indentation device is a device that measures resistance to indentation in bone.

NEW REGULATION NUMBER: 21 CFR 888.1600

CLASSIFICATION: Class II

PRODUCT CODE: QGQ

BACKGROUND

DEVICE NAME: OsteoProbe

SUBMISSION NUMBER: DEN210013

DATE DE NOVO RECEIVED: March 31, 2021

SPONSOR INFORMATION:

Active Life Scientific, Inc.
1027 Garden Street
Santa Barbara, California 93101

INDICATIONS FOR USE

The OsteoProbe is indicated for use as a measurement tool to measure bone tissue resistance to microindentation on the tibia in adults. The clinical significance of resistance to microindentation is unknown. This device is not intended to diagnose or treat any clinical condition.

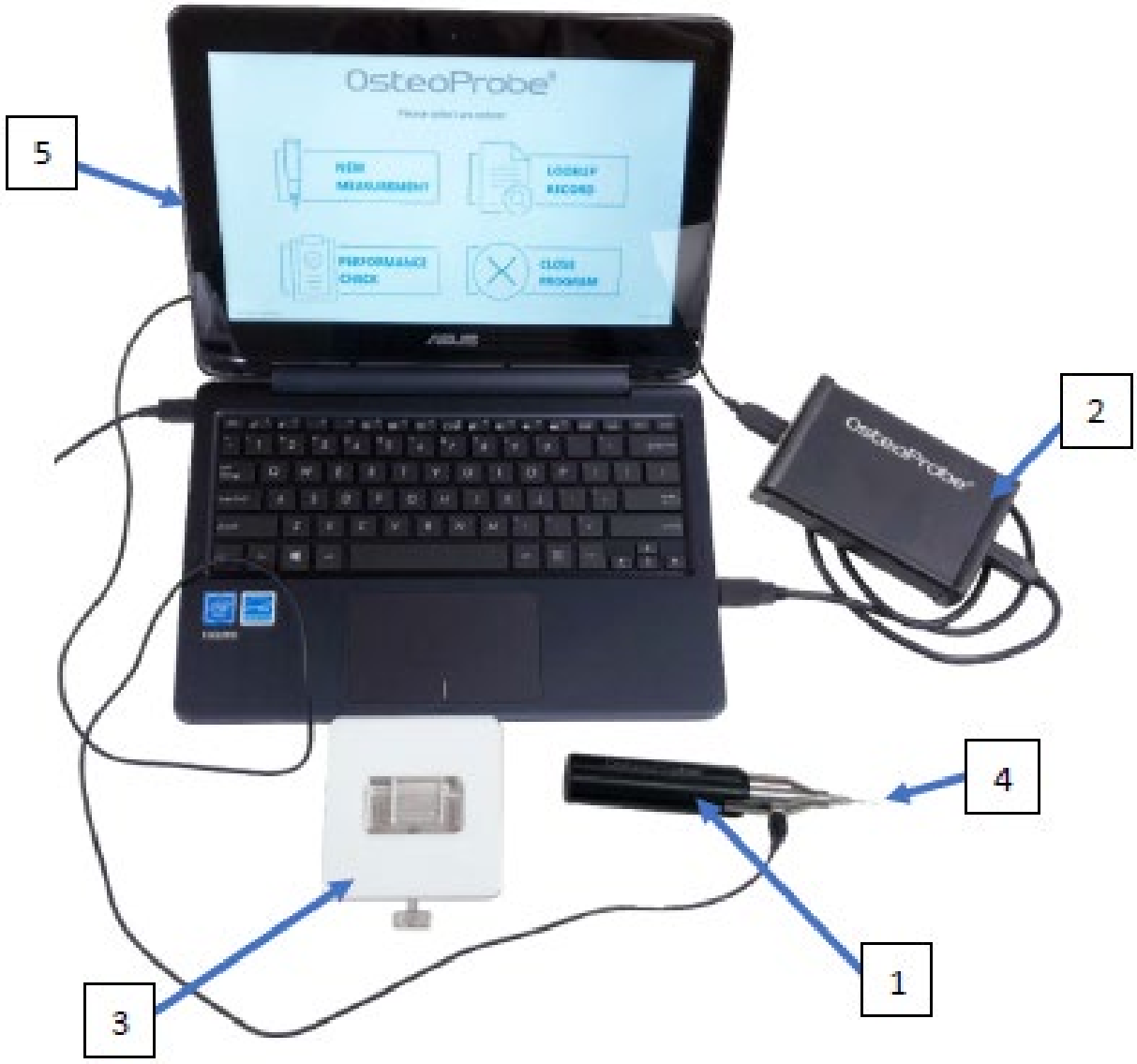
LIMITATIONS

The sale, distribution, and use of the OsteoProbe are restricted to prescription use in accordance with 21 CFR 801.109.

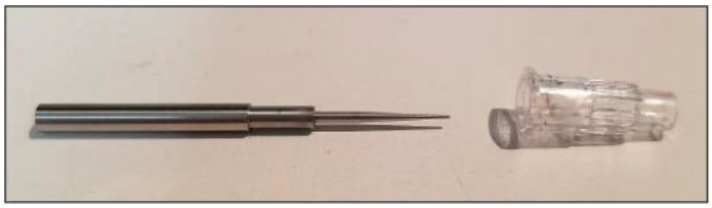
PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The OsteoProbe is a cortical bone microindentation measurement tool based on reference point indenter technology. System hardware consists of a Stylus (1), an Electronics Adapter (2), a Reference Block Holder and single-use Reference Block (3), a single-use disposable Tip Assembly (4), and an Operator Interface (5).



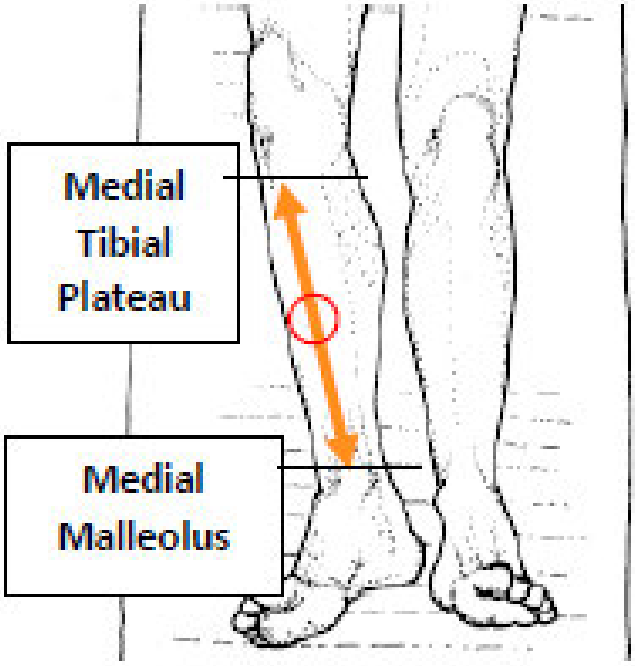
The single-use Tip Assembly (image below) consists of a polycarbonate Guide and stainless steel Tip, which are both steam sterilized by the user. The 28-guage solid Tip is made of AISI 440C stainless steel with a 90° conical tip and <10 μm tip sharpness radius.



A single-use Sterile Cover is an accessory that enables use with sterile technique, shown over the Stylus in the image below. After the Sterile Cover is placed over the Stylus, the sterile Tip Assembly (Tip and Guide) is inserted into the Stylus through an access hole in the Sterile Cover. The Guide is secured to the Stylus via a Luer lock connection, retaining the Tip within the Stylus.

Device Operation

The device is used within a full sterile procedure and must be performed by a trained operator. With the patient in decubitus supine position, the user orients the tibia such that the flat surface of the medial tibia diaphysis is horizontal. The operator marks the mid-point between the medial border of the tibial plateau and the medial malleolus, then disinfects a wide area. The red circle in the image below shows the target area. The operator administers a local anesthetic subcutaneously and at the periosteal surface. Using sterile technique, the operator secures a sterile Tip Assembly in the Stylus, through a hole in the Sterile Cover. The user holds the Stylus and pierces the skin above the flat surface of the medial tibia, pushing down through the periosteum to reach the bone surface.



Keeping the Stylus within 10° normal to the bone surface, the operator pushes downward with increasing force until an impact mechanism within the Stylus triggers, at 10 N. A spring-loaded hammer within the Stylus impacts the proximal end of the Tip with 40 N of force. Impact takes about 0.25 milliseconds, with the Tip creating an indentation in the bone about 400 µm deep.

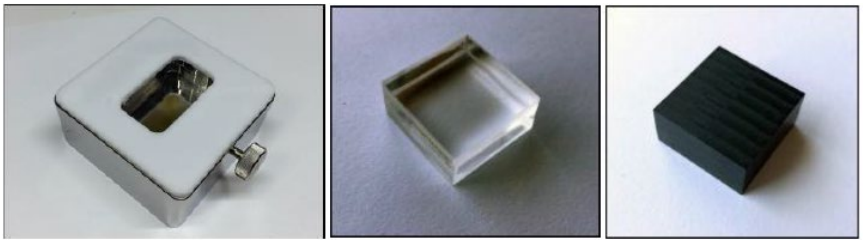
Without pulling the Tip out of the skin, the operator moves the Tip to a new location and repeats the indentations until the software indicates that patient indentations are complete. All indentations are typically performed within a 1 cm^2 area. After patient measurements are complete, the operator makes 10 indentations on the Reference Block.

The OsteoProbe measures displacement. For each indentation, the Electronics Adapter acquires the analog signal from a strain gage sensor within the Stylus, converts it to a digital representation of displacement, and transmits it to the software on the Operator Interface laptop. The Electronics Adapter connects the Stylus to the Operator Interface using USB cables. The device generates a Bone Score™ output in units of **B**one **M**aterial **S**trength **i**ndex (BMSi), a measure of the resistance to microindentation in bone:

$$\text{BMSi} = \frac{100 \times (\text{Mean indentation distance into plastic Reference Block})}{(\text{Mean indentation distance into patient bone})}$$

The device also outputs the standard deviation for both patient bone measurements and plastic Reference Block measurements.

The clear Reference Block is composed of polymethylmethacrylate (PMMA), shown in the image below next to the Reference Block Holder. The PMMA Reference Block and has a reference BMSi value of 100.



The image above also shows a black Performance Check Block, made of Noryl with a reference BMSi value of 73. Every 30 days, a performance check must be conducted on a Performance Check Block. The purpose of this performance check is to ensure the device is performing as expected without the need to ship equipment back to the manufacturer for service. The acceptance criterion for a performance check is 73 ±1.5 BMSi.

The OsteoProbe physical measurement limits are BMSi from 27 to 158. The range of BMSi values in the current patient experience (n = 905 patients) is BMSi = 45 to 102.

Software Description

The OsteoProbe software resides on the Operator Interface laptop. The software includes a patient setup screen that allows for the operator to enter the Tip ID and non-identifiable patient information. This information is stored along with the measurement data read from the device. After patient information is entered, the software displays a measurement screen that guides the operator through the measurement process. The Operator Interface collects and displays data from the Stylus via a USB cable and Electronics Adapter.

After 8 indentations, the software determines the median value and checks if all 8 indentations are within ±15 BMSi units of the median. If all 8 indentations do not fall within 15 BMSi units of the median, additional indentations are requested. The software recalculates the median after each indentation until 8 indentations are within 15 units of the median. The software allows a maximum of 18 indentations to obtain the minimum of 8 indentations within 15 BMSi units of the median.

In addition to audible tones, a visual representation of completed and remaining indentations is displayed. After indentations are complete, a measurement report screen is displayed. The measurement report displays the calculated Bone Score™. Standard deviations of the indentations on the patient and reference material are displayed for quality assurance purposes. Data are saved to a local log that can be accessed via a lookup report.

The software will indicate when a performance check is required and will not allow new measurements to be made until a performance check is completed. The software also monitors the device performance and may suggest a performance check if it detects a potential issue.

SUMMARY OF NON-CLINICAL/BENCH TESTING

BIOCOMPATIBILITY / MATERIALS

The OsteoProbe includes one patient-contacting component, a stainless steel tip per AISI 440C.

This external communicating component contacts tissue/bone with limited exposure (≤ 24 hours). Biocompatibility evaluation has been completed according to FDA Guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM348890.pdf). The Tip test articles were found non-cytotoxic per ISO 10993-5. The test articles were found to be non-sensitizing in tests for skin sensitization per ISO 10993-10. The test articles were found to be non-irritating in tests for irritation per ISO 10993-10. The test articles were found not to have acute systemic toxicity per ISO 10993-11. The test articles were found to be non-pyrogenic per ISO 10993-11.

All other components of the device system are not patient-contacting.

PACKAGING, STERILIZATION, CLEANING, AND SHELF LIFE

Packaging

None of the device components are provided sterile, packaging adequacy was solely verified by simulated transport testing. Automated actuator equipment was used to compare device performance before and after exposure to transport processes to evaluate adequacy of the device packaging. The packaged reusable system was subject to compression, shock (20 drops from 30 inches), and vibration (90 minutes random). After testing there was no visible damage and,

- The average measurement before testing was BMSi = 72.4 and after testing was BMSi = 73.0, which met the acceptance criterion of 73±1.5.
- The % change in strain gage calibration constant after testing was 0.716%, which met the acceptance criterion of <5%.

Tip Assembly boxes was subject to compression, shock (20 drops from 30 inches), and vibration (90 minutes random). The largest shipment possible was tested, 8 Tip Assembly boxes (160 Tip Assemblies). There was no major damage to Tip Assembly boxes, and there was no damage to Tip Assemblies.

Sterility

OsteoProbe Tip Assembly Sterilization

The OsteoProbe Tip Assemblies are single use devices provided non-sterile and should be cleaned and sterilized prior to use. Steam sterilization methods per AAMI ST79 (Comprehensive guide to steam sterilization and sterility assurance in health care facilities) and ISO17665-1, Half Cycle Method (Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation and routine control of

a sterilization process for medical devices) were validated to ensure a sterility assurance level (SAL) of 10^{-6}.

OsteoProbe Reusable Components Reprocessing

All OsteoProbe reusable components are provided non-sterile and should be cleaned prior to use. Reprocessing validation was performed on the Stylus, Stylus USB cable, and Reference Block Holder.

After soiling test articles with defibrinated blood soil, the articles were cleaned with Super Sani-Cloth Germicidal Disposable Wipes per the User Manual instructions for use. Cleaning validation resulted in no visible soil seen after cleaning, and hemoglobin and protein testing of extracts passed the acceptance criteria of hemoglobin level < 2.2 $\mu g/cm^2$ and protein level < 6.4 $\mu g/cm^2$.

Test articles were inoculated using (b) (4) bovine serum with the following organisms: (b) (4) (b) (4) Intermediate level disinfection validation resulted in bioload reduction via extracts testing that passed the acceptance criteria: a log reduction of ≥ (b) (4) logs for (b) (4) a log reduction of ≥ (b) (4) ogs for (b) (4)

Shelf Life

Accelerated aging testing was performed on the OsteoProbe reusable components per ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. The service life of two years was verified by accuracy testing after accelerated aging.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

Electrical safety and electromagnetic compatibility testing has been performed per IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) CAN/CSA-C22.2 No. 60601-1:14IEC 60601- 1:2005, Medical electrical equipment Part 1: General requirements for basic safety and essential performance and IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – collateral standard: electromagnetic compatibility – Requirements and tests. The test results support electrical safety and electromagnetic compatibility.

SOFTWARE

The OsteoProbe software documentation was reviewed according to the FDA Guidance document, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued May 11, 2005. The software was found to have a Moderate Level of Concern, because a failure of the device may result in a minor injury to a patient

prior to risk mitigation. The software documentation included management of cybersecurity and:

1. Software Description
2. Device Hazard Analysis
3. Software Requirements Specification
4. Architecture Design Chart
5. Software Design Specification
6. Traceability Analysis
7. Software Development Environment Description
8. Verification and Validation Documentation
9. Revision Level History
10. Unresolved Anomalies

The software documentation provided in support of the OsteoProbe was found to be acceptable.

PERFORMANCE TESTING

Strain gage sensor testing was performed with comparison to a calibrated micrometer. (b) (4) strain gages were subjected to (b) (4) measurements each at (b) (4) (b) (4), representing the physiological range of indentation depths. This testing resulted in sensor linearity of (b) (4), average accuracy = (b) (4), and precision = (b) (4) average deviation (SD=(b) (4)). These results indicated that the linear equation used for calculating BMSi is appropriate.

Accuracy and precision tests were performed to characterize the (b) (4) sources of variability: device, operator, bone, and clinical use environment. The sponsor performed one-way random effects analysis of variation (ANOVA) to obtain point estimates of variability for each source.

Device Variability Testing

An automated actuator was used to conduct variability testing on (b) (4) devices, using Noryl reference blocks only, to eliminate variable effects of the operator, indented material, and clinical use environment.

Five measurements each were made, for a total of (b) (4) data points. Difference from the target value of (b) (4) BMSi was evaluated. Results (mean difference from the target value) showed device accuracy (b) (4) BMSi units, SD=(b) (4). The sponsor performed one-way random effects ANOVA to obtain the point estimate of Device Variability (b) (4) BMSi units (b) (4)

Operator Variability Testing

Operator variability testing was performed per ISO 5725 Accuracy (trueness and precision) of measurement methods and results, across (b) (4) different laboratories with a

different operator/device used at each lab. Labs with difference experience levels were included, from least experienced to most experienced. Testing was conducted using (b) (4) reference polymer materials, to cover the range of expected patient measurements (range was (b) (4) BMSi from 905 patients in prior clinical research): (b) (4) . Each lab measured the (b) (4) materials (b) (4) times, in randomly assigned order, different order across the labs, and all testing performed within (b) (4) hour at each lab.

Results showed operator accuracy (bias) was < (b) (4) BMSi units (range (b) (4)). Operator Repeatability was SD=(b) (4) BMSi units, and operator Reproducibility was SD=(b) (4) BMSi units. The one-way ANOVA point estimate of Operator Variability = (b) (4) BMSi units (b) (4)

Cortical Bone Variability Testing

Bone variability testing was conducted using 5 bare-bone specimens from each of (b) (4) animal models: porcine tibia, ovine tibia, and bovine femur. Testing on these (b) (4) specimens included (b) (4) BMSi measurements, with (b) (4) individual sets of measurements made on each bone depending on spe n size. The coefficient of variation was determined for each of the (b) (4) bone specimens, which ranged from (b) (4) (b) (4)

Results showed the average coefficient of variation and standard deviation range were:
Porcine tibia average (b) (4)
Ovine tibia average (b) (4)
Bovine femur average (b) (4)

The one-way ANOVA point estimate of Bone Variability = (b) (4) BMSi units (b) (4) to (b) (4)

Because the bare bone variability testing did not include soft tissue, the sponsor conducted testing using simulated soft tissue and simulated skin and adipose tissue testing, to determine if soft tissue could add significant variability. A single operator tested a single device in various layers of a simulated soft tissue (Simulated Tissue #TSS-10 from Simulab Corporation) placed over a Noryl block, to simulate different thicknesses of soft tissue, from (b) (4) in (b) (4) increments. Results after (b) (4) measurements each indicated negligible effect of soft tissue surrogate on BMSi measurements. Layer thickness did not appear to affect the BMSi measurements.

A single operator tested a (b) (4) device through simulated skin and adipose tissue, basic tissue plate (adult skin and subcutaneous fat – 8N #141811 from SynDaver). Results from (b) (4) measurements each through the simulated tissue and without tissue indicated negligible effect of the skin and adipose tissue surrogate on BMSi measurements.

Clinical Use Environment Variability Testing

The sponsor provided clinical data to support device precision (repeatability and reproducibility), including a Swedish clinical study specifically design to assess reproducibility, a summary of prior clinical experience up to December 2020, and US clinical safety study.

In the study of (b) (4) Swedish female subjects aged 75-80 years, (b) (4) ubjects were measured (b) (4) in the same leg during the same patient visit. (b) (4) operators performed this testing. Using (b) (4) different operators, half ((b) (4) subjects) were measured (b) (4) by the same operator, to obtain intra-operator variability. Using a different pair of (b) (4) operators, half (b) (4) subjects) were measured (b) (4) by (b) (4) operator and then again by a different operator, to obtain inter-operator variability. The one-way ANOVA to obtain point estimates of intra- and inter-operator variability were:
Repeatability: Intra-Operator Variability = (b) (4)
Reproducibility: Inter-Operator Variability = (b) (4)

Generalizability of these results from Swedish women to the larger intended use population was demonstrated by comparison to the US clinical study results (n= (b) (4) subjects, G200139) and a broader set of clinical experience from studies outside the US as well as previous US clinical studies (n=905 subjects). The table below shows the range of device measurements, along with the age range and sex from each dataset.

BMSi Range in Three Datasets

Dataset	**BMSi Range**	**Age Range, years**	**Male/Female**
Swedish Study (n= (b) (4)	60-92	75-80	0/120
Complete clinical experience to December 2020 (n=905)	45-102	18-99	368/537
US clinical study (G200139; n= (b) (4)	62-89	32-79	10/30

The bar graph below shows the distribution of BMSi readings from the n=905 complete clinical experience dataset, with the dot representing the mean of (b) (4) BMSi units and the vertical bar representing (b) (4) the standard deviation of (b) (4) BMSi units. The bold horizontal lines show the range of the Swedish study, (b) (4) to (b) (4) BMSi units, which overlaps with (b) (4) f measurements from the entire dataset.

(b) (4)

The distribution of BMSi readings from the n=905 complete clinical experience dataset, when split between females and males, is shown. The Swedish study range of (b) (4) BMSi overlaps nearly all of the n (b) (4) female data from the larger dataset, and also overlaps the majority of the male data.

Examining age similarly, the table and plot show that the Swedish study range of (b) (4) BMSi units spans the majority of data from each age group in the larger n=905 dataset.

The clinical use environment variability testing from the Swedish study appear to be generalizable to the intended use population of the OsteoProbe, based on the study results BMSi range being comparable to the broader clinical experience and Investigational Device Exemption (IDE) study results, including examination by sex and age.

Environmental Conditions Testing

Testing was conducted to assure the OsteoProbe accuracy remained acceptable across the range of temperature and humidity conditions for operation and storage, 10°C to 30°C and 20% to 80% relative humidity, non-condensing. Testing was conducted to assure the

OsteoProbe accuracy remained acceptable across the range of temperature and humidity conditions for transport, -20°C to 50°C and 10% to 90% relative humidity, non-condensing.

USABILITY TESTING

Usability testing was conducted to ensure all critical tasks are successfully performed. The critical tasks were identified via a Use-Related Risk Analysis, consisting of tasks that could result in serious or higher severity harm, where a serious harm results in injury or impairment requiring professional medical intervention. Physicians, physician assistants, and nurses were evaluated in (b) (4) use scenarios, 1) Prepare for procedure and perform micro-indentation test; and 2) Dispose of and disinfect materials. The participants were also evaluated in a knowledge task scenario, instructional materials interpretation.

The identified hazards that could result in a serious or higher harm were inappropriate medical intervention, falling heavy object, or pathogen exposure. The results are shown in the table below, where the average score is the average pass rate for the critical tasks in each scenario.

Usability Testing Results

Scenario	Average Score
(b) (4)	

The usability testing was used to make improvements to eliminate risks or respond to user observations. These include incorporation of the sterile cover to allow both operator hands to remain sterile, and modification of the user interface to automatically open the OsteoProbe software when the device is turned on. The usability testing resulted in no unacceptable residual risks remaining in the updated risk analysis.

SUMMARY OF CLINICAL INFORMATION

The sponsor conducted a US clinical trial under IDE G200139, *A Single-Arm, Open Label Clinical Study to Collect Safety Data on the OsteoProbe System When Used as A Measurement Tool*, to understand the device's safety profile.

A total of 40 subjects were enrolled at a single center in the study as the Safety Cohort and none of the subjects were discontinued early. A total of 42 subjects were screened for potential participation in the study. Two (2) subjects were screen failures and neither had the OsteoProbe procedure or were enrolled into the study. All 40 subjects were evaluated out to 30 days, the primary endpoint. Subject age ranged from 22 to 73 years old, with a mean of 46. The mean BMI for subjects was 29.75. The subjects included 30 females and 10 males. Race/ethnicity of the

subjects were: 32 (80%) Caucasian/Non-Hispanic, 2 (5%) Caucasian/Hispanic, 2 (5%) Asian/Non-Hispanic, 1 (2.5%) Asian/Caucasian/Non-Hispanic, 1 (2.5%) Black/African American/Non-Hispanic, 1 (2.5%) Native American/Non-Hispanic, and 1 (2.5%) Native Hawaiian/Non-Hispanic. All 40 subjects had an average Numerical Rating Score (NRS, range 0-10) for Pain prior to the procedure of 0.

The primary endpoint was defined as the incidence of device-related serious adverse events (SAEs) in subjects evaluated with the OsteoProbe. The primary hypothesis is that the probability of experiencing a device-related SAE for subjects treated with the investigational device is smaller than the performance goal of 1%. Historical data of (b) (4) subjects from four prior clinical trials served as a Bayesian informative prior, in which no device-related SAEs were observed. The performance goal would be achieved if the Bayesian posterior probability is higher than (b) (4) that the device-related SAE rate is less (i.e., better) than the performance goal; this would occur if zero device-related SAEs are observed.

Secondary endpoints included:

- Numerical Rating Score Pain at Procedure, 1-day, 7-day, and 30-day visits;
- BSMi scores after the Procedure;
- Adverse event rates through Day 30;
- Device-related adverse events through Day 30;
- SAE through Day 30; and
- Unanticipated adverse device effects (UADE) through Day 30.

Results showed the primary endpoint was found to be successful, as no device-related SAEs (b) (4) were observed in the study. There were no SAEs, or UADEs. The NRS pain post-procedure n average of (b) (4) after the procedure. There was one adverse event (AE) in one subject (b) (4) in (b) (4) categorized as mild in severity, possibly related to the investigational device and possibly related to the investigational procedure. In this AE, the subject rated pain after the procedure as a (b) (4) on the scale of (b) (4) which resolved the same day without any treatment.

The clinical test results indicated minimal risk to adult patients when the OsteoProbe is used to measure bone resistance to microindentation.

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 OsteoProbe labeling includes the following: device description, indications for use, summary of clinical studies, instructions for use, description of the operator training program that must be completed prior to use, contraindications, warnings, precautions, shelf life, disposal instructions, and technical specifications. The labeling meets the requirements of 21 CFR 801.109 for prescription devices. The labeling also includes validated reprocessing instructions for the reusable components, and sterilization instructions for the single-use components. The

labeling includes information regarding the limitations of clinical significance of device output, as well as a summary of the accuracy and precision of the device.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a bone indentation device and the measures necessary to mitigate these risks.

Identified Risks to Health	Mitigation Measures
Bone fracture or soft tissue damage	In vivo performance testing Labeling
Adverse tissue reaction	Biocompatibility evaluation
Infection, including operator exposure to infectious transmission	Shelf-life testing Sterilization validation Reprocessing validation Human factors testing Labeling
Patient or operator injury due to electrical hazards	Electrical safety testing Electromagnetic compatibility (EMC) testing
Pain, discomfort, bruising or bleeding	In vivo performance testing Labeling
Inappropriate patient management due to inaccurate device output or misinterpretation of device output	Non-clinical performance testing In vivo performance testing Software verification, validation, and hazard analysis Human factors testing Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the bone indentation device is subject to the following special controls:

(1) In vivo performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must evaluate the risk of bone fracture, soft tissue damage, pain, discomfort, bruising, or bleeding.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including an evaluation of the accuracy and precision of the device with respect to resistance to bone indentation.

(3) Human factors testing must demonstrate that the intended user(s) can correctly use the device, based on the instructions for use.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Performance testing must demonstrate:
   (i) The sterility of the patient-contacting components of the device; and
   (ii) Validation of reprocessing instructions for any reusable components of the device.

(6) Performance data must support the shelf life of the device by demonstrating continued sterility and device functionality over the identified shelf life.

(7) Software verification, validation, and hazard analysis must be performed.

(8) Performance data must be provided to demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

(9) Labeling must include:
   (i) Instructions for use;
   (ii) Validated methods and instructions for reprocessing of any reusable components;
   (iii) A shelf life for any sterile components;
   (iv) Information regarding limitations of the clinical significance of the device output; and
   (v) A detailed summary of the accuracy and precision of the device.

BENEFIT/RISK DETERMINATION

The risks of the device are based on nonclinical laboratory studies as well as data collected in clinical studies described above. Types of harmful risks include bone fracture, soft tissue damage, pain, discomfort, bruising, or bleeding. In the clinical study, only one of the 40 subjects experienced an AE after the procedure, which was pain that was mild in severity and resolved the same day without any treatment.

The probable benefits of the device are also based on nonclinical laboratory studies as described above. Specifically, the device obtains an accurate measurement of resistance to bone microindentation.

The sponsor has collected adequate data to assess the safety profile of the subject device and identified that there are benefits (e.g., obtaining an accurate measurement of resistance to bone microindentation).

PATIENT PERSPECTIVES

Patient perspectives considered for the OsteoProbe were obtained from self-reported pain scores in the IDE clinical trial. Of the 40 subjects, only one reported pain occurring within hours of the procedure, at a level of 1 on a 0-10 NRS scale. That subject's pain resolved without intervention or treatment within the following five hours. For the entire study group, the NRS pain was an average of 0 (± 0.2) after the procedure.

Benefit/Risk Conclusion

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

> "The OsteoProbe is indicated for use as a measurement tool to measure bone tissue resistance to microindentation on the tibia in adults. The clinical significance of resistance to microindentation is unknown. This device is not intended to diagnose or treat any clinical condition."

The probable benefits outweigh the probable risks for the OsteoProbe. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the OsteoProbe is granted and the device is classified as follows:

Product Code: QGQ
Device Type: Bone indentation device
Regulation Number: 21 CFR 888.1600
Class: II