



August 19, 2021

Active Life Scientific, Inc.
Alexander Proctor
Chief Technology Officer
1027 Garden Street
Santa Barbara, California 93101

Re: DEN210013
Trade/Device Name: OsteoProbe
Regulation Number: 21 CFR 888.1600
Regulation Name: Bone indentation device
Regulatory Class: Class II
Product Code: QGQ
Dated: March 29, 2021
Received: March 31, 2021

Dear Alexander Proctor:

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 OsteoProbe, a prescription device under 21 CFR Part 801.109 with the following 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. The device is not intended to diagnose or treat any clinical condition.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the OsteoProbe, and substantially equivalent devices of this generic type, into Class II under the generic name bone indentation device.

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.

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 March 30, 2021, FDA received your De Novo requesting classification of the OsteoProbe. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the OsteoProbe 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 FDA has determined that, for the previously stated indications for use, the OsteoProbe 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:

Identified Risk	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 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

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.

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

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.

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 bone indentation device they intend to market prior to marketing the device.

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Stephen Himley at 240-402-9557.

Sincerely,

CAPT Raquel Peat, Ph.D., M.P.H., USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health