June 28, 2022

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

Re: K221195
Trade/Device Name: OsteoProbe
Regulation Number: 21 CFR 888.1600
Regulation Name: Bone Indentation Device
Regulatory Class: Class II
Product Code: QGQ
Dated: June 6, 2022
Received: June 7, 2022

Dear Alexander Proctor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Laura C. Rose, PhD
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221195

Device Name
OsteoProbe

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Device Trade Name: OsteoProbe

Manufacturer: Active Life Scientific, Inc.
1027 Garden Street, Santa Barbara, CA 93101

Contact: Alexander Proctor
Chief Technology Officer
Phone: 805-770-2600 x109
Email: alex@activelifescientific.com

Date Prepared: 6/23/2022

Classification: 21 CFR §888.1600, Bone indentation device
Class: II

Product Code: QGQ

Predicate Devices: OsteoProbe – DEN210013

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.

Device Description: OsteoProbe® is a bone microindentation measurement tool. It is a prescription device per 21 CFR Part 801.109. The device includes a single-use disposable component and reusable components. The single-use disposable component has a Spaulding classification of critical and is provided sterile. The reusable components have a Spaulding classification of non-critical and must be reprocessed (cleaning and intermediate-level disinfection) between each use. The device has one accessory: a single-use, disposable sterile cover.

Substantial Equivalence:
The subject OsteoProbe device is substantially equivalent to the predicate device with respect to indications, function, and performance. The sterilization, distribution, shelf-life, and biocompatibility of the single-use disposable of the subject device are substantially equivalent to the predicate device and do not raise different questions of safety and effectiveness.

Preclinical Testing:
The following validations and testing were performed on the OsteoProbe device:

- Sterilization validation testing (AAMI TIR28, ISO 10993-7, & ISO 11135)
- Distribution Testing (ASTM D4169, ASTM D4332-1)
- Shelf Life (ASTM F1980, ASTM F2096, ASTM F88)
- Biocompatibility
    - Cytotoxicity (ISO 10993-5)

- Sensitization (ISO 10993-10)
- Irritation/Intracutaneous Reactivity (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)
- Rabbit Pyrogen-Material Mediated (ISO 10993-11)

Clinical Testing:
Clinical testing was not necessary to support equivalence.

Conclusion:
The subject OsteoProbe device is substantially equivalent for its intended use to the previously-cleared, predicate device.