September 11, 2025

Active Life Scientific, Inc.
Alexander Proctor
Chief Technology Officer
228 West Carrillo Street
Suite A
Santa Barbara, California 93101

Re: K250216
Trade/Device Name: OsteoProbe (OP-100)
Regulation Number: 21 CFR 888.1600
Regulation Name: Bone Indentation Device
Regulatory Class: Class II
Product Code: QGQ
Dated: September 8, 2025
Received: September 8, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2025.09.11 10:31:46 -04'00'

Jesse Muir, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250216

Device Name

OsteoProbe (OP-100)

Indications for Use *(Describe)*

The OsteoProbe is a measurement tool intended to assess bone tissue resistance to microindentation on the tibia of adults, reported as the Bone Material Strength Index (BMSi). In laboratory studies, BMSi measurements have been shown to correlate with biomechanical properties of bone, including whole-bone strength and fracture toughness. The clinical significance of laboratory-based biomechanical studies is unknown. The device is not intended to diagnose disease, predict fracture risk, or treat any clinical condition. Prescription use only, by or on the order of a physician.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

K250216

Device Trade Name: OsteoProbe®

Manufacturer: **Active Life Scientific, Inc.**
228 West Carrillo Street, Suite A
Santa Barbara, CA 93101

Contact: Alexander Proctor
CTO
+1-805-770-2600 x109

Prepared by: MCRA, LLC
803 7th Street, NW, 3rd Floor
Washington, DC 20001
Office: 202.552.5800

Date Prepared: August 28, 2025

Classifications: **21 CFR 888.1600**

Class: II

Product Codes: QGQ

Primary Predicate: OsteoProbe®

Additional Predicate: N/A

Indications For Use:
The OsteoProbe is a measurement tool intended to assess bone tissue resistance to microindentation on the tibia of adults, reported as the Bone Material Strength Index (BMSi). In laboratory studies, BMSi measurements have been shown to correlate with biomechanical properties of bone, including whole-bone strength and fracture toughness. The clinical significance of laboratory-based biomechanical studies is unknown. The device is not intended to diagnose disease, predict fracture risk, or treat any clinical condition. Prescription use only, by or on the order of a physician.

Device Description:
OsteoProbe is a bone microindentation device. 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.

Predicate Device:
Active Life Scientific, Inc. submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, OsteoProbe is substantially equivalent in design principles and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: OsteoProbe [K221195]
Additional Predicate: N/A

Performance Testing Summary:
Performance testing on cadavers was completed to demonstrate correlations between BMSi measurements and biomechanical properties of bone, including whole-bone strength, 3-point bending, and fracture toughness testing following ASTM standards.

A total of 67 tibia, 67 femur, 54 radii, and 53 L4 vertebrae were able to be successfully harvested from cadaveric donors for testing. Fracture toughness testing was completed on 18 machined beams from the midshaft of each tibia. For tissue level testing, 66 beams were machined from the unbroken anterior midshaft of each femur.

The primary endpoint was the correlation between OsteoProbe measurement on the tibia (clinically indicated site) vs bone strength of the femoral neck, distal radius, and L4 vertebrae.

The secondary endpoints were:

- Tissue-level Traditional Mechanical Testing:
    - Fracture Toughness Testing: The correlation between OsteoProbe measurements and Fracture Toughness.
    - 3-point bending of machined beams: The correlation between OsteoProbe measurements and traditional mechanical testing.

In summary, the key findings of the study are:

- **Primary Endpoint**: OsteoProbe measurements showed statistically significant correlations with bone strength at the femoral neck, distal radius, and L4 vertebrae, establishing a statistically significant relationship with hip, wrist, and spine strength.

- **Tissue-Level Mechanical Testing**:
    - OsteoProbe strongly correlated with fracture toughness.
    - It also correlated with key mechanical properties, including fracture force, work to fracture, ultimate stress, elastic modulus, and stiffness.

The results of this study robustly demonstrate the significant correlation between OsteoProbe and biomechanical properties and highlight their value in accurately assessing both bone tissue strength and overall whole bone strength.

Substantial Equivalence:
There are no differences between the subject device and the predicate, other than the proposed indication for use.

Conclusion:
The subject device and the predicate devices have identical technological characteristics and materials. The subject and predicate devices are packaged and sterilized using identical methods. The data included in this submission demonstrate the substantial equivalence to the predicate devices listed above. OsteoProbe is as safe, as effective, and performs as well as, or better, than the predicate device. The correlation with biomechanical properties of bone, such as whole-bone strength and fracture toughness has been established.