March 28, 2023

Implanet, S.A.
℅ Kelliann Payne
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K230026
Trade/Device Name: SQUALE
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: March 9, 2023
Received: March 9, 2023

Dear Kelliann Payne:

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,

Katherine D. Kavlock -S

for

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal 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: 06/20/2023
See PRA Statement on last page

510(k) Number *(if known)*

K230026

Device Name

SQUALE

Indications for Use *(Describe)*

The SQUALE devices are indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The SQUALE devices are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and are to be implanted via an open, anterior approach.

The SQUALE devices are intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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K230026
510(k) SUMMARY
Implanet, S.A.'s SQUALE

Implanet, S.A.
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Phone: + 33 557 995 555

Contact Person: Régis Le Couëdic

Date Prepared: March 12, 2023

Name of Device: SQUALE

Common or Usual Name: Cervical Intervertebral Body Fusion Device

Regulatory Class: 21 CFR 888.3080

Product Code: ODP

Predicate Devices

- Primary Predicate: Stryker's AVS AS PEEK Spacer (K142251)
- Additional Predicate: SpineUp, Inc Romero Cervical Cage (K212358)
- Additional Predicate: RTI Surgical, Fortilink™-C with TETRAfuse™ 3D Technology (K163673)

Intended Use / Indications for Use

The SQUALE devices are indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The SQUALE devices are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and are to be implanted via an open, anterior approach.

The SQUALE devices are intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Technological Characteristics

The SQUALE device consists of Polyetherketoneketone (PEKK) (compliant with ASTM F2820 standard) cervical cages of various widths and heights, which can be inserted between two cervical or cervico-thoracic vertebral bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be filled with autogenous and/or allogenic bone graft.

Performance Data

Performance testing was conducted per ASTM F2077 and ASTM F2267. Specifically, Implanet performed static and dynamic axial compression testing, static and dynamic compression shear testing, static and dynamic torsional testing, subsidence testing, and expulsion testing. The results of these studies were determined to be substantially equivalent to legally marketed devices.

Substantial Equivalence

The SQUALE is as safe and effective as the primary predicate device, Stryker AS AVS PEEK spacer. The SQUALE has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the SQUALE and its predicate device raise no new issues of safety or effectiveness and are covered by the proposed secondary predicate device. Performance data demonstrate that the SQUALE is as safe and effective as the predicate device. Thus, the SQUALE is substantially equivalent.

Conclusions

The SQUALE is intended to treat degenerative disc disease, and bench testing demonstrates that it is as safe, as effective, and performs as well as the primary predicate device.