March 19, 2024

Sapphire Medical Group, LLC
Nicholas Ruggiero
Quality Regulatory Consultant
32565B Golden Lantern Street Suite 113
Dana Point, California 92629

Re: K232619
Trade/Device Name: MATRIX HA PEEK Cervical IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: February 14, 2024
Received: February 27, 2024

Dear Nicholas Ruggiero:

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.

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,

Brent Showalter -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232619

Device Name

MATRIX HA PEEK Cervical IBF System (Multiple)

Indications for Use *(Describe)*

The Matrix HA PEEK Cervical Implant System is intended for spinal fusion procedures at multiple contiguous levels (C2 to T1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are intended to be packed with autogenous bone graft. The Matrix HA PEEK cervical implant system is intended to be used with a supplemental fixation system.

Additionally, the use of hyperlordotic devices (lordotic angle greater than 8°) are intended to be used exclusively with anterior supplemental fixation.

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.

510(k) Summary

As required by section 807.92(c)

Sapphire Medical Group, LLC is requesting marketing clearance for the Matrix HA PEEK Cervical Implant System

A. Sponsor/Manufacturer: Sapphire Medical Group, LLC
Org ID: 480296
Nicholas Ruggiero, Consultant
32565 B Golden Lantern Street, Suite 113
Dana Point, CA 92629
440-281-1853 Phone

B. Trade Name: Matrix HA PEEK Cervical Implant System
Common Name: Spinal Implant
Classification Name: Spinal intervertebral body fusion device (21 CFR 888.3080 Class II,Product Code ODP)

C. Predicate Device: K192316 (Matrix HA PEEK Cervical Implant System)

D. Device Description:

Matrix HA PEEK Cervical IBF devices are manufactured from Hydroxyapatite (HA) filled Polyetheretherketone (PEEK). The specific material is PEEK-OPTIMA HA Enhanced manufactured by Invibio. The Matrix HA Cervical IBF Devices superior and inferior surfaces have ridges designed to interface with the vertebral endplates to help resist rotation and migration. Tantalum (ASTM F560) or titanium (ASTM F136) rods are located at the extremes of the Matrix HA Cervical IBF Devices to allow for radiological confirmation of the device positioning. The anterior face of each interbody has a recessed horizontal slot encapsulating a 6/32 threaded thru hole which is to be used to interface with the inserter. Each device has a uniform wall thickness of 2.5mm.

Matrix HA PEEK Cervical IBF Devices are available in multiple configurations to coincide with the surgical approach and patient needs: parallel, 7° thru 20° lordotic angle and convex. The Matrix HA PEEK Cervical IBF Devices are open rectangular devices with curved lateral walls and rounded edges. The devices are open with cavities to facilitate bony ingrowth.

E. Intended Use:

The Matrix HA PEEK Cervical Implant System is intended for spinal fusion procedures at multiple contiguous levels (C2 to T1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are intended to be packed with autogenous bone graft. The Matrix HA PEEK cervical implant system is intended to be used with a supplemental fixation system.

Additionally, the use of hyperlordotic devices (lordotic angle greater than 8°) are intended to be used exclusively with anterior supplemental fixation.

F. Technological Characteristics:

The fundamental technological characteristics of the Matrix HA PEEK Cervical IBF Devices are identical to the cleared device.

G. Non-clinical Testing:

Testing according to ASTM F2077-18 was performed on the previously cleared Matrix HA PEEK Cervical IBF Devices. The tests included static compression, dynamic compression, static torsion and dynamic torsion. Additional testing per ASTM F2077-18 was performed on the proposed Matrix HA PEEK Cervical IBF Devices to establish substantial equivalence in mechanical function and properties to the cleared device.

H. Conclusion:

The fundamental scientific technology of the Matrix HA PEEK Cervical Implant system and the proposed device allows for substantial equivalency between them.