January 14, 2026

Sync Surgical
% Daniel Johnson
Regulatory Engineer
DJJ Consulting LLC
10301 Lake Ave
Cleveland, Ohio 44102

Re: K252219
Trade/Device Name: Cervical Interbody and VBR Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, PLR, MQP
Dated: December 22, 2025
Received: December 22, 2025

Dear Daniel Johnson:

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,

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)*

K252219

Device Name

Cervical Interbody and VBR Fusion System

Indications for Use *(Describe)*

The Sync Cervical Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Sync VBR Fusion System is a vertebral body replacement system indicated for use in skeletally mature patients to replace a collapsed, damaged, diseased, or unstable vertebral body due to tumor or trauma (i.e. fracture) or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues. The device is intended for use in the cervical spine (from C3 to C7) and in the thoracolumbar spine (from T1-L5). The device is intended for use with supplemental fixation cleared by the FDA for use in the cervical, thoracic, or lumbar spine and is to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

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) #: K252219

510(k) Summary

Prepared on: 2025-12-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Sync Surgical
Applicant Address	5705 Eastman Drive Plano TX 75093 United States
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Applicant Contact Email	shawnc@arfabricating.com
Correspondent Name	DJJ Consulting LLC
Correspondent Address	10301 Lake Ave Cleveland OH 44102 United States
Correspondent Contact Telephone	216-333-2127
Correspondent Contact	Mr. Daniel Johnson
Correspondent Contact Email	danieljacobj@gmail.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Cervical Interbody and VBR Fusion System
Common Name	Intervertebral body fusion device Spinal intervertebral body fixation orthosis
Classification Name	Intervertebral Fusion Device With Bone Graft, Cervical Spinal Vertebral Body Replacement Device
Regulation Number	888.3080 and 888.3060
Product Code(s)	ODP, PLR, MQP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K1 63494	Summit Spine Channel Cervi calnterbody Fusion System	ODP
K191778	Omnia Medical VBR	PLR
K241494	Pantheon Pedicle Screw and Iliac Bolt Fixation System	NKB

Device Description Summary

21 CFR 807.92(a)(4)

The Sync Cervical Interbody Fusion System is an anterior interbody fusion device for use in the cervical spine (C2-T1). The Sync VBR Fusion System is a vertebral body replacement device for use in the cervical and thoracic spine. Interbody and VBR Fusion components are available in a variety of heights and footprints to suit the individual pathology and anatomy of the patient. The device components are made from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or PEEK conforming to ASTM F2026. The PEEK interbody fusion

device components have tantalum marker pins manufactured from tantalum per ASTM F560 for radiographic visualization.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Sync Cervical Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Sync VBR Fusion System is a vertebral body replacement system indicated for use in skeletally mature patients to replace a collapsed, damaged, diseased, or unstable vertebral body due to tumor or trauma (i.e. fracture) or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues. The device is intended for use in the cervical spine (from C3 to C7) and in the thoracolumbar spine (from T1-L5). The device is intended for use with supplemental fixation cleared by the FDA for use in the cervical, thoracic, or lumbar spine and is to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device indications are the same as the predicate device indications

Technological Comparison 21 CFR 807.92(a)(6)

The subject and predicate devices have the same technological characteristics

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Mechanical performance of the Sync Cervical Interbody and VBR Fusion System was evaluated based on the FDA recommendations in the Spinal Systems Guidance for and product codes ODP, PLR, and MQP. Mechanical testing including static and dynamic axial compression and torsion per ASTM F2077, subsidence per ASTM F2267, and expulsion testing were performed on the worst-case device in the system.

There is no clinical testing being submitted with this application.

The subject device is substantially equivalent to the predicate devices in mechanical performance.