November 20, 2024

Pro Surgical, Inc.
Jason Blain
Chief Executive Officer
1910 Palomar Point Way, Suite 201
Carlsbad, California 92008

Re: K242517
Trade/Device Name: ProAM ACDF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: August 23, 2024
Received: October 24, 2024

Dear Jason Blain:

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242517

Device Name

ProAM ACDF System

Indications for Use *(Describe)*

The ProAM ACDF System is a standalone intervertebral body fusion system intended for spinal fusion procedures of the cervical (C2-T1) spine in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and imaging studies (radiographs, CT, MRI).

The ProAM ACDF System is intended to be used at multiple contiguous levels of the cervical spine (C2-T1). The implant is designed to accommodate two screws. Two screws should be used to ensure adequate fixation of the implant.

The ProAM ACDF System is intended for use on patients who have had at least six weeks of nonoperative treatment. It is intended to be used with autogenous and/or allogeneic bone graft comprised of cortical, 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) Summary

510(k) Number K242517

Date Prepared: October 24, 2024

Submitted By

Pro Surgical, Inc.
1910 Palomar Point Way, Suite 201
Carlsbad, CA 92008
760-542-2333

Contact:
Jason Blain
jblain@pro-surgical.com
858-761-6262

Device Name

Device Trade Name:	ProAM ACDF System
Common Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Fusion Device with Integrated Fixation, Cervical
Device Class:	Class II
Regulation Number:	12 CFR § 888.3080
Product Code:	OVE

Predicate Devices

Primary Predicate Device
Astura DOLOMITE Anterior Cervical Stabilization System – K202065

Additional Predicate Devices
SeaSpine Shoreline ACS Interbody System – K233414
Pro Surgical ProAM ALIF System – K240126
Globus Coalition – K151939

Device Description

The ProAM™ ACDF System is an intervertebral body fusion system that consists of an intervertebral body fusion device manufactured from titanium alloy (Ti-6Al-4V conforming to ASTM F3001) and screws manufactured from titanium alloy (Ti-6Al-4V conforming to ASTM F136).

The intervertebral body fusion device has a cross-sectional shape that is trapezoidal, and the device is otherwise box-shaped in stature with cavities for containment of bone graft material. The device is available in sizes that vary in footprint size, height, and lordotic angle. It is meant for direct anterior insertion and has 2 holes through which screws are placed to affix to bone. All devices have an open, porous architecture throughout and a pyramidal textured porous surface at the endplate contacting surfaces that helps prevent device migration.

The screws are available in various diameters and lengths. Screws engage the vertebral bodies by passing through the intervertebral body fusion device and into bone. They are turned to fixate to the bone.

Indications for Use

The ProAM ACDF System is a standalone intervertebral body fusion system intended for spinal fusion procedures of the cervical (C2-T1) spine in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and imaging studies (radiographs, CT, MRI).

The ProAM ACDF System is intended to be used at multiple contiguous levels of the cervical spine (C2-T1). The implant is designed to accommodate two screws. Two screws should be used to ensure adequate fixation of the implant.

The ProAM ACDF System is intended for use on patients who have had at least six weeks of nonoperative treatment. It is intended to be used with autogenous and/or allogeneic bone graft comprised of cortical, cancellous, and/or corticocancellous bone graft.

Indications for Use Comparison

The Indications for Use of the ProAM ACDF System are identical to those for the listed predicate devices.

Technological Comparison

The ProAM ACDF System is substantially equivalent to the predicate devices when considering design, configurations and sizes, intended use, material composition, manufacture, function, and mechanical performance.

Performance Data

The following mechanical testing was performed:

Static and dynamic compression testing per ASTM F2077
Static and dynamic compression-shear testing per ASTM F2077
Static and dynamic torsion testing per ASTM F2077
Subsidence testing per ASTM F2267
Expulsion

The mechanical testing demonstrated that the device performs as well or better than the predicates.

Conclusions

The ProAM ACDF System is substantially equivalent to the legally marketed predicate devices based on a comparison of indications for use, design, intended use, material composition, function, and mechanical performance.