



March 8, 2024

Astura Medical
Parker Kelch
Quality Manager
4949 West Royal Ln
Irving, Texas 75063

Re: K233359

Trade/Device Name: DOMINION Expandable Corpectomy System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP, PLR
Dated: February 9, 2024
Received: February 9, 2024

Dear Parker Kelch:

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

Indications for Use

510(k) Number (if known)

K233359

Device Name

DOMINION Expandable Corpectomy System

Indications for Use (Describe)

The DOMINION Expandable Corpectomy System is indicated for vertebral body replacement in the cervical spine (C2-T1) and the thoracolumbar spine (T1-L5). The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion.

When used in the cervical spine (C2-T1), DOMINION spacers are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor fracture or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in the cervical degenerative disorders. These spacers are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion. The System is intended to be used with supplemental fixation that has been cleared by the FDA for use in the cervical spine.

When used in the thoracolumbar spine (T1-L5), DOMINION spacers are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

The system is intended to be used with supplemental fixation that has been cleared by the FDA for use in the thoracolumbar spine (i.e. posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems).

When used at more than two levels, supplemental fixation should include posterior 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: DOMINION Expandable Corpectomy System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	September 29, 2023
Submitted By	Astura Medical 4949 W Royal Ln Irving, TX 75063
Contact	Parker Kelch 4949 W Royal Ln Irving, TX 75063 Phone: 469-501-5530 x503 Email: parker@asturamedical.com
Trade Name	DOMINION Expandable Corpectomy System
Common Name	Expandable Corpectomy Spacer
Classification Name	Spinal Vertebral Body Replacement Device
Class	II
Product Code	MQP, PLR
CFR Section	21 CFR section 888.3060
Device Panel	Orthopedic
Primary Predicate Device	ALTA Anterior Cervical Corpectomy Spacer (K190426)
Reference Predicate Device(s)	DOLOMITE Anterior Cervical Stabilization System (K202065) FORTIFY Corpectomy Spacer (K173982) OLYMPIC Posterior Screw Fixation System (K153446)
Device Description	The Dominion Expandable Corpectomy system is a modular system comprised of Expandable Columns, Modular Endplates, and optional screws. The primary purpose of the Expandable Column is to provide mechanical support to the anterior column of the spine after a vertebral corpectomy is performed. The primary function of the Modular Endplates is to provide attachment points for the Expandable Column to the vertebral endplates. The screws are an optional device that can provide enhanced fixation to the vertebral endplates when desired. The system contains Inserters which allow the insertion and expansion of the Expandable Columns.
Materials	Titanium Alloy (Ti6-AL4-V ELI) per ASTM F136 Nitinol #1 (ASTM F2063)
Technological characteristics	Compared to the ALTA corpectomy spacer, the Dominion has the capability to expand to the desired height to suit patient anatomy. Once expanded its primary purpose of mechanical support to the anterior column of the spine is equivalent to that of the static ALTA corpectomy spacers.
Substantial Equivalence Claimed to Predicate Devices	The DOMINION Expandable Corpectomy System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

Indications for Use	The DOMINION Expandable Corpectomy System is indicated for vertebral body replacement in the cervical spine (C2-T1) and the thoracolumbar spine (T1-L5). The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion. When used in the cervical spine (C2-T1), DOMINION spacers are intended for use in skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor fracture or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in the cervical degenerative disorders. These spacers are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion. The System is intended to be used with supplemental fixation that has been cleared by the FDA for use in the cervical spine. When used in the thoracolumbar spine (T1-L5), DOMINION spacers are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. The system is intended to be used with supplemental fixation that has been cleared by the FDA for use in the thoracolumbar spine (i.e. posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.
Non-clinical Test Summary	The following analyses were conducted: 1. ASTM F2077 - Static compression 2. ASTM F2077 - Dynamic compression 3. ASTM F2077 - Static Torsion 4. ASTM F2077 - Dynamic Torsion 5. Expulsion (Push-Out) 6. ASTM F2267 - Subsidence
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-Clinical and Clinical	Astura Medical considers the DOMINION Expandable Corpectomy Spacer to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.