March 3, 2022

Medynus Inc.
% Jeena Mathai
President
Eerkie Corporation
4027 Runnymeade Dr
Collegeville, Pennsylvania 19426

Re: K220379
Trade/Device Name: IMPEACE and IMPEACE-Uni Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 9, 2022
Received: February 10, 2022

Dear Jeena Mathai:

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,

Colin O’Neill, M.B.E.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220379

Device Name
IMPEACE and IMPEACE-Uni Anterior Cervical Plate System

Indications for Use *(Describe)*

The IMPEACE and IMPEACE-Uni Anterior Cervical Plate System is intended for anterior fixation to the cervical spine C2-C7. The specific clinical indications include:

- degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

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

Medynus Inc.
IMPEACE and IMPEACE-Uni Anterior Cervical Plate System

Sponsor:	Manufacturer	Medynus Inc. 18 Technology Dr. Ste 109 Irvine, CA 92618 Phone: (949) 932-0847 Email: davidshin@medynus.com
	Official Contact	Jeena Mathai Eerkie Corporation 4027 Runnymeade Dr Collegeville, PA 19426 Phone: (760) 521-5870 Email: mgsharemg@gmail.com
Date Prepared:	February 9, 2022	
Device Name:	IMPEACE and IMPEACE-Uni Anterior Cervical Plate System	
Common Name:	Anterior Cervical Plate System	
Classification Name:	Spinal Intervertebral Body Fixation Orthosis	
Classification Number:	21 CFR 888.3060	
Product Code/Classification:	KWQ, class II	

Description:

The IMPEACE and IMPEACE-Uni Anterior Cervical Plate System consists of a variety of shapes and sizes of Main Plates, screw, lock-plate and the associated instruments. The lock-plate is pre-assembled to the main plate and designed to prevent screws from backing out. Each component is subjected to a color anodizing process to differentiate the screw type and diameter and to make the surgical process easy. The plates range in length to accommodate one and two-level procedures for IMPEACE-UNI and one, two, three, and four level procedures for IMPEACE. Main plate is available from 13mm to 46mm for IMPEACE-UNI and 10mm to 112mm for IMPEACE. Screws are available in lengths from 12mm to 20mm for IMPEACE-UNI and 10mm to 20mm in 2mm increments for IMPEACE. The screws have either a 4.5mm or 5.1mm diameter for IMPEACE-UNI and 4.0mm or 4.5mm diameter for IMPEACE. They are fixed self-tapping, variable self-tapping screw, fixed self-drilling screw, variable self-drilling.

The IMPEACE and IMPEACE-Uni Anterior Cervical Plate System components are supplied non-sterile, are single use and are fabricated from titanium allow (Ti-6Al-4V ELI) that conforms to ASTM F136.

Intended Use:	The IMPEACE and IMPEACE-Uni Anterior Cervical Plate System is intended for anterior fixation to the cervical spine C2-C7. The specific clinical indications include: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.
Predicate Device:	Huvexel - FORTIS and HANA Anterior Cervical Plate System (K173099)
Substantial Equivalence:	The IMPEACE and IMPEACE-Uni Anterior Cervical Plate System is identical to the predicate device and is as safe and effective as the Huvexel - FORTIS and HANA Anterior Cervical Plate System. The Subject device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. There are no technological differences between the Subject device and its predicate devices resulting in no new issues of safety or effectiveness. Thus, the Medynus IMPEACE and IMPEACE-Uni Anterior Cervical Plate System is identical/substantially equivalent.
Performance Data:	The subject and predicate devices are identical and therefore, no performance testing is required. Submission is only transferring name of a system that has already been cleared under K173099. No testing is required.
Conclusion:	The Medynus IMPEACE and IMPEACE-Uni Anterior Cervical Plate System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. Thus, the subject device is identical/substantially equivalent to the predicate device.