October 13, 2022

Dio Medical Corporation
Milan George
VP of R&D
2100 Campus Lane
Suite 100
East Norriton, Pennsylvania 19403

Re: K222448
Trade/Device Name: UNITY Sacroiliac Joint Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: August 12, 2022
Received: August 15, 2022

Dear Milan George:

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)*
K222448

Device Name
UNITY Sacroiliac Joint Fixation System

Indications for Use *(Describe)*

The UNITY Sacroiliac Joint Fixation System is indicated for use in skeletally mature patients for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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.***

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*"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

## Dio Medical
## UNITY Sacroiliac Joint Fixation System

| | | |
|---|---|---|
| Sponsor: | Manufacturer: | Dio Medical Corp.<br>2100 Campus Lane, Suite 100<br>East Norriton, PA 19403 |
| | Official Contact:<br>Email:<br>Phone: | Milan George<br>mgeorge@dio-us.com<br>1-877-394-5407 ext.102 |
| Date Prepared: | August 12, 2022 | |
| Device Name:<br>Common Name: | UNITY Sacroiliac Joint Fixation System<br>Sacroiliac Joint Fixation Screw | |
| Classification Name: | Smooth or threaded metallic bone fixation fastener | |
| Classification Number: | 21 CFR 888.3040 | |
| Product Code/ Classification: | OUR, class II | |
| Description: | The UNITY Sacroiliac Joint Fixation System consists of screws designed to enhance sacroiliac joint fusion. The UNITY Sacroiliac Joint Fixation System is offered in various diameters, lengths, and three screw types in cannulated form to accommodate patient anatomy. The three design types of the subject device are:<br>1. Standard Thread Screw (with and without slots)<br>2. Lag Screw (with and without slots) and<br>3. Washer Screw (with slots) | |
| Indications for Use: | The UNITY Sacroiliac Joint Fixation System is indicated for use in skeletally mature patients for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. | |
| Predicate Device: | Huvexel Co. Ltd. - UNITY Sacroiliac Joint Fixation System (K173201) | |

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| Substantial Equivalence: | The UNITY Sacroiliac Joint Fixation System has the same intended use, indications for use, and principles of operation as the primary predicate device. It has similar technological characteristics as its predicate device. There are no technological differences between the subject device and its predicate device resulting in no new issues of safety or effectiveness. Thus, the UNITY Sacroiliac Joint Fixation System is substantially equivalent to the predicate. |
| Performance Data: | The UNITY Sacroiliac Joint Fixation does not create a new worst case for device performance; additional testing is not needed. |
| Conclusion: | Based upon a comparison of technological characteristics, intended use, design features, and mechanical performance, the Dio Medical UNITY Sacroiliac Joint Fixation System does not raise any new safety or efficacy concerns and has demonstrated substantial equivalence to the identified predicates. |