February 26, 2026

Disior, Ltd.
% Edward Wells-Spicer
Senior Regulatory Affairs Specialist
Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, Colorado 80112

Re: K253764
Trade/Device Name: ENOS Software Guided External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: OSN
Dated: November 25, 2025
Received: November 25, 2025

Dear Edward Wells-Spicer:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253764

Please provide the device trade name(s).

ENOS Software Guided External Fixation System

Please provide your Indications for Use below.

The ENOS Software Guided External Fixation System application is used with the Paragon 28 Monkey Rings™ External Fixation System for the treatment of traumatic or reconstructive deformities within the indications for use of the Monkey Rings External Fixation System. It is used to generate a prescription of strut adjustments to provide to the patient.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

Manufacturer: Disior Ltd
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Contact: Aarno Jussila
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Phone: 720-994-5481

Date Prepared: February 25, 2025

Device Trade Name: ENOS Software Guided External Fixation System

Device Class and Common Name: Class II, Software for diagnosis/treatment

Classification: 888.3030 - Single/multiple component metallic bone fixation appliances and accessories

Product Codes: OSN

Indications for Use: The ENOS Software Guided External Fixation System application is used with the Paragon 28 Monkey Rings™ External Fixation System for the treatment of traumatic or reconstructive deformities within the indications for use of the Monkey Rings External Fixation System. It is used to generate a prescription of strut adjustments to provide to the patient.

Device Description: The ENOS Software Guided External Fixation System (also known as Smart Monkey Rings) is a cloud-based medical device software system that assists orthopedic surgeons in planning patient-specific deformity corrections for use with the Monkey Rings Circular External Fixation System. The surgeon enters anatomical alignment values, hardware configuration parameters, and treatment objectives, and the software's algorithm processes these inputs together with the mechanical characteristics of the Monkey Rings hardware to generate a patient-specific strut adjustment schedule.

Primary Predicate:	SixFix™ Hexapod Fixator and Deformity Analysis and Correction Software (DACS) (K190069)
Additional Predicate:	Orthohub External Fixator Software (K140550)
Substantial Equivalence:	The subject device and the primary predicate device have similar intended uses. Both the ENOS Software Guided External Fixation System and the Sixfix Hexapod primary predicate are intended to be used for traumatic (subject device) and post-traumatic injuries (primary predicate device). The subject device and the secondary predicate device are both intended for the treatment of traumatic or reconstructive deformities. The subject device and secondary predicate device have identical intended uses, except for the secondary predicate specifying reconstructive tibia deformities while the subject device is intended for reconstructive deformities within the Monkey Rings External Fixation System (K212895). The subject device, primary predicate device and the secondary predicate device generate a prescription of strut adjustments. The subject device and primary predicate have manual input methods to assist the surgeon calculating the lengths of the struts connecting the rings to manipulate the bone fragments. Also, for the subject and primary predicate, the software receives inputs from the physician and allows the physician to visualize the moving bone position. The subject and primary predicate program computes the strut lengths necessary to implement adjustments required by the surgeon. The output of the subject device is a prescription of strut adjustments, which is identical to the primary and secondary predicates. A difference between the subject device and secondary predicate is the use of a web-based software run in the cloud for the subject device and the use of a macintosh computer for the secondary predicate. Additionally, the secondary predicate utilizes x-rays in addition to manual surgeon input for calculations of recommended adjustments while the subject device is manual input only. The differences between the subject device and predicates do not introduce new issues of safety and effectiveness.
Performance Testing:	All necessary testing has been performed on the ENOS Software Guided External Fixation System to assure substantial equivalence to its predicate and demonstrate the subject device performs as intended. <u>Software Verification and Validation</u> Software verification and validation were carried out based on the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", at the unit, integration, and system levels to determine substantial equivalence to the predicate device. <u>Non-Clinical Bench Testing</u> Beyond Formal Verification Testing, incremental testing of software inputs against expected frame data was also performed. Given the number of anatomical sides, sites, ring combinations, and ring sizes possible, a mathematically randomized set of inputs over defined limits was selected to be used to validate that the software was developed to satisfy its intended purpose.

Conclusions:

Clinical data are not needed to support the safety and effectiveness of the subject device.

The subject device possesses similar intended uses, technological characteristics, and principles of operation as the primary predicate and secondary predicate devices. The subject device does not raise new issues of safety or effectiveness. The subject device is substantially equivalent to the legally marketed predicate devices.