June 28, 2022

Enztec Limited
% Nathan Wright, MS
Engineer and Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K220449
Trade/Device Name: DePuy CONDUIT™ LLIF SQUID Inserter
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: May 26, 2022
Received: May 27, 2022

Dear Nathan Wright:

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,

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

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)*
K220449

Device Name
DePuy CONDUIT™ LLIF SQUID Inserter

Indications for Use *(Describe)*
The DePuy CONDUIT™ LLIF SQUID Inserters are intended to be used with the EIT Cellular Titanium® LLIF Cages.

EIT Cellular Titanium® LLIF Cage
The EIT Cellular Titanium® LLIF Cages with a microscopic roughened surface and micro and nano-scale features are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. EIT Spine LLIF is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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.

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510(K) SUMMARY

Submitter's Name:	Enztec Limited
Submitter's Address:	3/17 Print Place Middleton, Christchurch 8024
Submitter's Telephone:	+64 27 829 2440
Contact Person:	Nathan Wright MS Empirical Testing Corp. 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	February 14, 2022
Trade or Proprietary Name:	DePuy CONDUIT™ LLIF SQUID Inserter
Common or Usual Name:	Implant insertion tool for intervertebral fusion device with bone graft, lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	OR: Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The DePuy CONDUIT™ LLIF SQUID Inserter is designed for use during Lumbar Interbody Fusion surgery, specifically using a lateral approach. The instrument has been designed specifically to interface with the EIT Cellular Titanium® Cages (K201605). The reusable instrument is provided non-sterile and made from commonly used orthopedic materials. There are no changes to the implants or to other instruments provided with the implants.

INDICATIONS FOR USE

The DePuy CONDUIT™ LLIF SQUID Inserters are intended to be used with the EIT Cellular Titanium® LLIF Cages.

EIT Cellular Titanium® LLIF Cage

The EIT Cellular Titanium® LLIF Cages with a microscopic roughened surface and micro and nano-scale features are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S 1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. EIT Spine LLIF is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

TECHNOLOGICAL CHARACTERISTICS

DePuy CONDUIT™ LLIF SQUID Inserters are made primarily from Stainless Steel per ASTM F899 (note: all implant contacting and patient tissue and bone contacting components are Stainless Steel per ASTM F899) with accessory components of other metal or plastic materials. The subject and predicate devices have nearly identical technological characteristics. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture (for implant- and patient-contacting components)
- Sterility
- Compatibility

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K210728	CONDUIT™ Instruments	DePuy Synthes	ODP, MAX	Primary
K201605	EIT Cellular Titanium® Cages	EIT Emerging Implant Technologies GmbH (with DePuy Synthes Spine)	ODP, MAX	Additional
K212823	DePuy CONDUIT LLIF Angled Inserters	Enztec Limited	MAX	Additional
K072791	Synthes Oracle Spacer	Synthes Spine	MAX, MQP	Additional

PERFORMANCE DATA

Non-clinical testing was conducted to confirm device performance per intended use including functionality bench test, impact test, thread endurance test, and formative usability test. The results of this non-clinical testing show that the performance of the DePuy CONDUIT™ LLIF SQUID Inserters are sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the DePuy CONDUIT™ LLIF SQUID Inserter is substantially equivalent to the predicate device.