September 1, 2023

Enztec Limited
% Nathan Wright, MS, RAC
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K232014
Trade/Device Name: CONDUIT™ ATP Inserters
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 11, 2023
Received: August 11, 2023

Dear Mr. 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 -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

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.*

Submission Number *(if known)*

K232014

Device Name

CONDUIT™ ATP Inserters

Indications for Use *(Describe)*

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

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.

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.**

# K232014 - 510(K) SUMMARY

| | |
|---|---|
| Submitter's Name: | Enztec Limited |
| Submitter's Address: | 3/17 Print Place<br>Middleton, Christchurch 8024 |
| Submitter's Telephone: | +64 27 829 2440 |
| Contact Person: | Nathan Wright MS, RAC<br>Empirical Technologies<br>719-351-0248<br>nwright@empiricaltech.com |
| Date Summary was Prepared: | July 6, 2023 |
| Trade or Proprietary Name: | CONDUIT™ ATP Inserters |
| Device Classification Name: | Implant insertion tool for intervertebral fusion device, lumbar |
| Classification & Regulation #: | Class II per 21 CFR §888.3080 |
| Product Code: | MAX |
| Classification Panel: | Spinal Devices (DHT6B) |

## DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The CONDUIT™ ATP Inserters are designed for use during Lumbar Interbody Fusion surgery, specifically using the ATP surgical approach. The inserters have been designed to interface with EIT Cellular Titanium® LLIF Cages (K201605). The reusable instruments are provided non-sterile and made from commonly used orthopedic materials with commonly used manufacturing processes. There are no changes to the implants or other compatible instruments provided with the implants.

## INDICATIONS FOR USE

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

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

The CONDUIT™ ATP Inserters are manufactured from Stainless Steel per ASTM F899 or ASTM A693 and Silicone per ESP Class VI. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are the same between the subject and predicates:

- Indications for use
- Materials of manufacture
- Sterility
- Compatibility

The differences in instrument handle design for surgeon utility and in handle materials and in the introduction of new instrument options (cobbs and spreaders) not previously part of the CONDUIT™ Inserter set do not

introduce any questions for safety and efficacy which were mitigated through the risk assessment and verification and validation testing.

**Predicate Devices**

| 510k Number | Trade or Proprietary or Model Name | Manufacturer | Predicate Type |
|---|---|---|---|
| K223671 | CONDUIT™ LLIF Straight Inserters | DePuy Synthes | Primary |

## PERFORMANCE DATA

Non-clinical testing was conducted to confirm the device performance per intended use including impaction endurance testing, formative usability testing, and thread cyclic testing. The results of this non-clinical testing show that the performance of the CONDUIT™ ATP Inserters is 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 CONDUIT™ ATP Inserters are substantially equivalent to the predicate device.