October 26, 2020

Indius Medical Technologies Pvt. Ltd.
℅ Nathan Wright
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K200937
Trade/Device Name: ACURA Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: September 25, 2020
Received: September 29, 2020

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,

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: 06/30/2020
See PRA Statement on last page.

510(k) Number *(if known)*
K200937

Device Name
ACURA Stabilization System

Indications for Use *(Describe)*

ACURA Stabilization System is intended to help provide immobilization and stabilization of spinal segments in skeletally mature patients (including small stature) and for pediatric patients as an adjunct to fusion using posterior pedicle screw fixation (T1-S2/Ilium), posterior hook fixation (T1-L5), or anterolateral fixation. These devices are indicated as an adjunct to fusion for the treatment of the following acute and chronic spinal instabilities or deformities:

1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. Degenerative spondylolisthesis
3. Trauma (fracture or dislocation)
4. Curvatures (Scoliosis, Kyphosis and /or Lordosis, Scheuermann's disease)
5. Spinal tumours
6. Spinal Stenosis
7. Pseudarthrosis
8. Previous Failed Fusions

When used as an adjunct to fusion, ACURA Stabilization System is intended to be used with autograft and/or allograft.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the ACURA Stabilization System is intended as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach.

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.

5. 510(K) SUMMARY

Submitter's Name:	Indius Medical Technologies Pvt. Ltd.
Submitter's Address:	Unit No. 12, Electronic Co-Operative Estate, Pune-Satara Road Pune – 411009, MH, India
Submitter's Telephone:	+91 20 29701607
Contact Person:	Nathan Wright MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	April 9, 2020
Trade or Proprietary Name:	ACURA Stabilization System
Common or Usual Name:	Thoracolumbosacral Pedicle Screw System
Classification:	Class II per 21 CFR §888.3070 and 21 CFR §888.3050
Product Code:	NKB, KWQ, KWP
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The ACURA Stabilization System is a single use implantable system consisting of connecting members (rods) and fixation members (screws, hooks). The hooks are available in different types based on the attachment points on the vertebra such as the Lamina and Transverse Process. The screws are available in multiple diameters and lengths based on variations in the spinal anatomy. Variants in screws are also available based on the surgical procedure requirement such as polyaxial screws, monoaxial screws, uniplanar screws, reduction screws, cannulated screws, fenestrated screws, long tab screws, dual outer diameter screws, iliac screws. Locking caps are available which lock the screw head onto the rods. These devices can be rigidly locked into a variety of configurations as per surgical conditions and are available in a variety of sizes to accommodate individual patient anatomy.

Screws mate with 5.5mm diameter rods. Screws, hooks and cross connectors are intended for posterior use only. Hooks are intended for posterior use only. Similarly, Screws, Rods and Cross-Connectors are intended for both posterior and lateral use.

The devices are made Medical Grade Titanium (Ti6Al4V per ASTM F136), with some rods and polyaxial screw heads also offered as cobalt chromium alloy (Co28Cr6Mo per ASTM F1537).

The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.

INDICATIONS FOR USE

ACURA Stabilization System is intended to help provide immobilization and stabilization of spinal segments in skeletally mature patients (including small stature) and for pediatric patients as

an adjunct to fusion using posterior pedicle screw fixation (T1-S2/Ilium), posterior hook fixation (T1-L5), or anterolateral fixation. These devices are indicated as an adjunct to fusion for the treatment of the following acute and chronic spinal instabilities or deformities:

1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. Degenerative spondylolisthesis
3. Trauma (fracture or dislocation)
4. Curvatures (Scoliosis, Kyphosis and /or Lordosis, Scheuermann's disease)
5. Spinal tumours
6. Spinal Stenosis
7. Pseudarthrosis
8. Previous Failed Fusions

When used as an adjunct to fusion, ACURA Stabilization System is intended to be used with autograft and/or allograft.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the ACURA Stabilization System is intended as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach.

TECHNOLOGICAL CHARACTERISTICS

The ACURA Stabilization System is made from titanium alloy per ASTM F136 or cobalt chrome alloy per ASTM F1537. 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 identical between the subject and predicates:

- Indications for Use
- Technological Characteristics
- Component Styles
- Materials
- Sizes
- Manufacturing & Biocompatibility

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K142381	Xia® 3 Spinal System	Stryker Spine	Primary
K110280	REVLOK™ Fenestrated Screw System	Globus Medical Inc.	Additional
K193365	M.U.S.T. Pedicle Screw System	Medacta International SA	Additional

K180458	FOCUS Pedicle Screw System	Nvision Biomedical Technologies, LLC	Additional
K131802	EXPEDIUM® Spine System	DePuy Spine, Inc.	Additional
K180210	CREO® Stabilization System	Globus Medical Inc.	Additional
K133350	REVERE® Stabilization System	Globus Medical Inc.	Additional

PERFORMANCE DATA

The ACURA Stabilization System has been tested in the following test modes:

- Static compression bending per modified ASTM F1717-18
- Static torsion per ASTM F1717-18
- Dynamic compression bending per ASTM F1717-18
- Axial grip testing per ASTM F1798
- Torsional grip testing per ASTM F1798

The results of this non-clinical testing show that the strength of the ACURA Stabilization System 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 ACURA Stabilization System is substantially equivalent to the predicate device.