March 24, 2020

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

Re: K200224
Trade/Device Name: SEA-LINK Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 27, 2020
Received: January 29, 2020

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,

Colin O'Neill, M.B.E.
Acting 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)*
K200224

Device Name
SEA-LINK Anterior Cervical Plate System

Indications for Use *(Describe)*

The SEA-LINK Anterior Cervical Plate System is intended for temporary stabilization of the anterior cervical spine (C2-C7) during the development of cervical spinal fusion achieved through ACDF (Anterior Cervical Discectomy & Fusion) or corpectomy in patients with:
•Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
•Trauma (including fractures)
•Tumors
•Deformity defined as kyphosis, lordosis or scoliosis
•Pseudarthrosis
•Failed Previous Fusions
•Spondylolisthesis
•Spinal Stenosis

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 Consulting 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	27-Jan-2020
Trade or Proprietary Name:	SEA-LINK Anterior Cervical Plate System
Common or Usual Name:	Anterior Cervical Plate System
Classification:	Class II per 21 CFR §888.3060
Product Code:	KWQ
Classification Panel:	Orthopedics

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The SEA-LINK Anterior Cervical Plate System is a single use implantable device to assist in the stabilization of the cervical spine during cervical spinal fusion. The device consists of plates and bone screws and is designed to prevent the bone screws from backing out after implantation.

The SEA-LINK Anterior Cervical Plate is designed to fit the lordosis of the cervical spine and to fit the curved medio – lateral anatomy of the spine. The SEA-LINK Anterior Cervical Plate System accommodates from single Level up to five-Level. The plate lengths range from 19mm to 114mm (end to end length) with a width and thickness of 17mm and 2.1mm respectively.

The screws offered are of self-drilling and self-tapping variations. The screws offered are variable angle and fixed angle thus providing four (4) types of screws. The screw diameters are 4mm and 4.5mm. The screw lengths range from 10mm to 20mm. A locking mechanism consisting of a cam fixed atop the plate is used to prevent screw back out.

The device is made from Medical Grade Titanium Alloy (Ti6Al4V, ASTM F136).

INDICATIONS FOR USE

The SEA-LINK Anterior Cervical Plate System is intended for temporary stabilization of the anterior cervical spine (C2-C7) during the development of cervical spinal fusion achieved through ACDF (Anterior Cervical Discectomy & Fusion) or corpectomy in patients with:
•Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)

•Trauma (including fractures)
•Tumors
•Deformity defined as kyphosis, lordosis or scoliosis
•Pseudarthrosis
•Failed Previous Fusions
•Spondylolisthesis
•Spinal Stenosis

TECHNOLOGICAL CHARACTERISTICS

The SEA-LINK Anterior Cervical Plate System is made from titanium alloy that conforms to ASTM F136. 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
- Materials of manufacture
- Sizes
- Principles of Operation

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K070775	Providence Anterior Cervical Plate System	Globus Medical Inc.	Primary
K103491	Skyline Anterior Cervical Plate System	A Johnson & Johnson Company	Additional
K134104	Terrace™ Anterior Cervical Plate System	CoreLink, LLC	Additional

PERFORMANCE DATA

The SEA-LINK Anterior Cervical Plate System has been tested in the following test modes:

- Static compression bending per ASTM F1717-18
- Static torsion per ASTM F1717-18
- Dynamic compression bending per ASTM F171-18

The results of this non-clinical testing show that the strength of the SEA-LINK Anterior Cervical Plate 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 SEA-LINK Anterior Cervical Plate System is substantially equivalent to the predicate device.