April 28, 2020

CoreLink, LLC
% Mr. Nathan Wright
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K200863
Trade/Device Name: Tiger® Occipital-Cervical-Thoracic Spinal Fixation System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: March 31, 2020
Received: April 1, 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, MBE
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

4. INDICATIONS FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020

Indications for Use

510(k) Number *(if known)*
K200863

Device Name
Tiger® Occipital-Cervical-Thoracic Spinal Fixation System

Indications for Use *(Describe)*

The Tiger Occipital-Cervical-Thoracic Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct into fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability of deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Tiger Occipital-Cervical-Thoracic Spinal Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advance stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Tiger Occipital-Cervical-Thoracic Spinal Fixation System may be connected to the components in the Tiger Spine System using the side by side and end to end rod to rod connectors.

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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5. 510(K) SUMMARY

Submitter's Name:	CoreLink, LLC
Submitter's Address:	2072 Fenton Logistics Blvd St. Louis, MO 63026
Submitter's Telephone:	888-349-7808
Contact Person:	Nathan Wright Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	31-Mar-2020
Trade or Proprietary Name:	Tiger® Occipital-Cervical-Thoracic Spinal Fixation System
Common or Usual Name:	OCT System
Classification:	Class II per 21 CFR 888.3075 and 21 CFR 888.3050
Product Code:	NKG, KWP
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Tiger® Occipital-Cervical-Thoracic Spinal Fixation System is an implant system used to provide temporary immobilization and stabilization of the cervical spine and occipito-cervico-thoracic junction while fusion occurs. The Tiger Occipital-Cervical-Thoracic Spinal Fixation System consists of screws, rods, hooks, plates, and connectors in various configurations which can be assembled to create a construct that meets the need of the patient. It can be used for single or multiple level fixation. Spinal rods and hooks may be contoured intraoperatively to meet specific anatomical requirements.

Implants in the Tiger® Occipital-Cervical-Thoracic Spinal Fixation System are manufactured from titanium alloy Ti-6Al-4V per ASTM F136 and cobalt chromium alloy Co-28Cr-6Mo per ASTM F1537.

INDICATIONS FOR USE

"The Tiger Occipital-Cervical-Thoracic Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct into fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability of deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Tiger Occipital-Cervical-Thoracic Spinal Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advance stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Tiger Occipital-Cervical-Thoracic Spinal Fixation System may be connected to the components in the Tiger Spine System using the side by side and end to end rod to rod connectors."

The indications for use for the Tiger® Occipital-Cervical-Thoracic Spinal Fixation System are similar to those of the predicates.

TECHNICAL CHARACTERISTICS

The Tiger® Occipital-Cervical-Thoracic Spinal Fixation System is made from Ti-6Al-4V that conforms to ASTM F136 and Co-28Cr-6Mo that conforms to 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 similar between the subject and predicates:

- Indications for use
- Technological characteristics
- Materials of manufacture
- Structural support mechanism
- Sizes

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K132504	Tiger® Occipital-Cervical-Thoracic Spinal Fixation System	CoreLink, LLC	Primary
K153631	Zimmer Virage® OCT Spinal Fixation System	Zimmer Spine, Inc.	Additional

PERFORMANCE TESTING SUMMARY

In support of this Special 510(k) Device Modification Premarket Notification, mechanical testing was not required because the worst case components were previously tested under the clearance for K132504.

CONCLUSION

The subject modified is Tiger® Occipital-Cervical-Thoracic Spinal Fixation System is identical to previously cleared Tiger® Occipital-Cervical-Thoracic Spinal Fixation System. The subject Tiger® Occipital-Cervical-Thoracic Spinal Fixation System has similar intended uses, indications, technological characteristics, and principles of operation as the predicate devices. The modifications do not raise any different questions of safety and effectiveness. The overall technology characteristics and mechanical performance data lead to the conclusion that the Tiger® Occipital-Cervical-Thoracic Spinal Fixation System is substantially equivalent to the predicate devices.