April 30, 2020

Elite Surgical Supplies (PTY) LTD
% Jordan Floyd
Project Engineer
JALEX Medical
27865 Clemens Rd. Suite 3
Westlake, Ohio 44145

Re: K200523
Trade/Device Name: Biolign® Roto-Loc Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 28, 2020
Received: March 2, 2020

Dear Jordan Floyd:

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 below.*

510(k) Number *(if known)*

K200523

Device Name

Biolign® Roto-Loc Cervical Plate System

Indications for Use *(Describe)*

The Biolign® Roto-Loc Anterior Cervical Plating System is indicated for use in the temporary stabilization of the cervical spine (C2-C7) during the development of solid spinal fusion in patients with instability caused by the following:

1. Degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies)
2. Trauma (including fractures)
3. Tumor
4. Spondylolisthesis
5. Spinal stenosis
6. Deformity (i.e., scoliosis, kyphosis, lordosis)
7. Pseudarthrosis
8. Failed previous fusions

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

| | |
|---|---|
| **Submitted By:** | Elite Surgical<br>54 De Havilland Crescent<br>Persequor Technopark<br>Pretoria, Gauteng ZA 0020 |
| **Date:** | 04/29/2020 |
| **Contact Person:** | Jordan Floyd, Project Engineer |
| **Contact Telephone:** | (440) 396-4041 |
| **Contact Fax:** | (440) 933-7839 |
| **Device Trade Name:** | Biolign® Roto-Loc Cervical Plate System |
| **Regulation Description:** | Spinal Intervertebral Body Fixation Orthosis |
| **Regulation Number:** | 21 CFR 888.3060 |
| **Device Classification:** | Class II |
| **Review Panel:** | Orthopedic |
| **Product Code:** | KWQ |
| **Primary Predicate Device:** | Orthofix 3 Degree ACP System (K012184)<br>The predicate device has never been subject to a recall. |
| **Additional Predicates:** | Medtech Spine Cure™ OPEL-C Plate System (K181543)<br>The reference predicate device has never been subject to a recall. |

**Device Description:**

The Biolign® Roto-Loc Cervical Plate system consists of cervical plates, locking caps, bone screws and all necessary instrumentation to implant the plate system. The system is manufactured from Titanium 6Al 4V (ISO 5832-3). A screw locking system is incorporated in the plate, allowing the surgeon to insert the screws, and afterwards locking the screws into place with the Biolign® Roto-Loc locking mechanism. This blocks the screw from backing out of the plate. The plates feature lordotic curvature and a transverse plane curvature for an anatomical fit to match patient pathology.

**Indications for Use:**

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2. Trauma (including fractures)
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5. Spinal stenosis
6. Deformity (i.e., scoliosis, kyphosis, lordosis)
7. Pseudarthrosis
8. Failed previous fusions

**Summary of Technological Characteristics:**

The Elite Surgical Cervical Plate System and the predicates have the same intended use and fundamental scientific technology. All devices compare similarly in:

- Design features
- Intended use
- Materials
- Dimensions
- Function

**Mechanical Testing:**

Substantial equivalence is supported by the results of mechanical testing including static and dynamic compression bending, and static torsion per ASTM F1717.

**Conclusion:**

Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.