DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 22, 2014

Jeil Medical Corporation
% Ms. Priscilla Chung
Official Correspondent
LK Consulting Group USA, Inc.
2651 E Chapman Avenue, Suite 110
Fullerton, CA 92831

Re: K130447
Trade/Device Name: Speedy Flap System
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Non-Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN, GXR
Dated: November 21, 2014
Received: November 24, 2014

Dear Ms. Chung:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S FDA

Carlos L. Peña, PhD, MS
Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K130447

Device Name
Speedy Flap System

Indications for Use *(Describe)*

Speedy Flap System is intended for use in the fixation of cranioplasty plates, covering burr holes, and fixation of cranial fractures.

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.

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510(k) Summary
(K130447)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

1. Date

December 17, 2014

2. Applicant

	Company
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3. Submission Contact Person

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4. Device Identification

- Proprietary Name – Speedy Flap System
- Common Name – Cranioplasty Plate Fastener
- Classification Name – Plate, Cranioplasty

5. Device Classification

- Classification: Class II
- Product Code: GXN, GXR
- Regulation Number: 21CFR882.5330, 21 CFR 882.5250

- Review Panel: Neurology

6. Predicate Devices

- 510(k) Number: K040864 and K122353
- Product Name: CranioFix and CranioFix 2 Titanium Clamp System
- Manufacturer's Name: Aesculap, Inc.

7. Device Description

The Speedy Flap is designed for the fixation of cranioplasty plates, covering burr holes, and fixation of cranial fractures. This device is made of the Titanium Alloy (ASTM F136). The Speedy Flap is composed of three parts: upper plate, lower plate and rod. This device supplied sterile and single use only.

8. Indication for Use

The Speedy Flap is intended for use in the fixation of cranioplasty plates, covering burr holes, and fixation of cranial fractures.

9. Substantial Equivalence Discussion

The Speedy Flap System has the same device characteristics, intended use, materials, design and use concept, sterilization, etc. as the predicate device, the CranioFix System. Only the dimensional specifications – shape, diameter and length – are slightly different. There are no technological differences that affect the safety or effectiveness of the device.

The table below compares the Speedy Flap System attributes with those of the predicate device.

Attribute	**Speedy Flap System**	**CranioFix and CranioFix 2 Titanium Clamp System**
510(k)	K130447	K040864 K122353
Manufacturer	Jeil Medical Coporation	Aesculap, Inc.
Intended use	The Speedy Flap System is intended for use in fixation of cranioplasty plates, covering burr holes, and fixation of cranial fractures.	The CranioFix System is intended for use in fixation of cranioplasty plates, covering burr holes, and fixation of cranial fractures.
Device Design	Clamp Outer Diameter SF-12F – 12mm SF-16F – 16mm	Clamp Outer Diameter FF490T – 11mm FF491T – 16mm

	SF-20F – 20mm	FF492T – 20mm
	Clamp Length SF-12F – 42.1mm, SF-16F – 43.3mm, SF-20F – 43.3mm	Clamp Length FF490T – 51.0mm, FF491T – 51.0mm, FF492T – 51.0mm
Technical Specification	Movement force between the Plate and the Rod: SF-12F: 141N SF-20F: 98N	 Cranio Fix2(11mm): 94N Cranio Fix2(20mm): 96N
	Separation force between the Plate and the Rod: SF-12F: 323N SF-20F: 198N	 Cranio Fix2(11mm): 312N Cranio Fix2(20mm): 147N
Biocompatibility	Acceptable	Acceptable
Composition of Material	Titanium Alloy Ti6Al4V ELI conforming to ASTM F136-11	Titanium Alloy Ti6Al4V ELI conforming to ASTM F136-11
Usage	Not Reusable	Not Reusable
Sterilization	Radiation Sterilization	Radiation Sterilization

The cranial plates and rods of the Speedy Flap System are substantially equivalent to the cranial plates and rods of its predicate Device, CranioFix System. There are no technological differences that affect the safety or effectiveness of the device.

10. Non-clinical testing

Test	Test Method	Results
Dimension Test	Measure the dimension of the test sample by Vernia-Calipus. The tolerance of the error range of the dimension shall be within ±5%.	within ±5%
Movement Force Test	Compress the axial load at the lower plate at a rate of 1mm/min. Measure the maximum load that the lower plate fixes.	Speedy Flap Syste ▪ SF-12F: 141N ▪ SF-20F: 98N CranioFix System: ▪ CranioFix 2 (11mm): 94N ▪ CranioFix 2 (20mm): 96N

Separation Force Test	Grip the rod of the system and apply compressive axial load at a rate of 1mm/min until the rod is separated from the plate.	Speedy Flap Syste ▪ SF-12F: 323N ▪ SF-20F: 198N CranioFix System: ▪ CranioFix 2 (11mm): 312N ▪ CranioFix 2 (20mm): 147N
Separation Force testing before and after rod cutting	Same test method as above. Compare test results between the sample with the rod and the sample with the rod cut	No significant change. The test results support that the upper disk will not be loosened after the rod cutting.
Climatic conditioning, Package performance, Visual inspections, Gross leak detection(bubble) and seal strength(peel) testing	The purpose of testing was to validate the ability of the package systems to protect the Speedy Flap System from hazards typically associated with the shipping and distribution environment. The testing was performed in accordance with the following standards. ▪ ASTM D4332-13 ▪ ASTM D5276-98 ▪ ASTM D642-00 ▪ ASTM D999-08 ▪ ASTM D4728-06 ▪ ASTM D6344-04 ▪ ASTM D5276-98 ▪ ASTM F1886/F1886M-09 ▪ ASTM F2096-11 ▪ ASTM F88/F88M-09	There were no anomalies throughout the conduct of the test and the test results of all the test samples support the suitability of the package configuration for the Speedy Flap System.
Chemical Analysis **Qualitative analysis of organic residual**	▪ SEM(Scanning Electron Microscopy) ▪ Gas chromatograph Mass spectrometer	▪ There was no other elements on the surface of the subject device other than the elements of the raw material(titanium alloy). ▪ The residual detected.
Shelf Life Test	Accelerated and real time shelf life testing were	The product met all acceptance criteria

	conducted to establish 3 year shelf life of the Speedy Flap System. Sterility, visual inspection, package integrity and the performance of the subject device were evaluated after aging.	
Sterilization Validation Test	Sterilization validation test was performed to validate the sterilization method for the Speedy Flap System. The testing was conducted in accordance with the following standards. ▪ ISO 11137-1 ▪ ISO 11137-2 ▪ ISO 11137-3	The sterilization method for the Speedy Flap System has been validated as effective through the study.

The test results of the movement force test and the seperation force test of the subject device were higher than the predicate devie; therefore, we conclude that the subject device performs as well as or better than the predicate device. Other testing results support that the subject device has a safety profile that is similar to the predicate devices.

11. Conclusions

Based on the information provided in this premarket notification, Jeil Medical Corporation concludes that Speedy Flap System has a safety and effectiveness profile that is similar to the legally marketed predicate devices.