May 29, 2020

Kono Seisakusho Co., Ltd.
% Akiko Dohi
Regulatory / Research Specialist
Ken Block Consulting
800 East Campbell Drive, Suite 202
Richardson, Texas 75081

Re: K192420
Trade/Device Name: Crownjun Nylon Suture
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable Polyamide Surgical Suture
Regulatory Class: Class II
Product Code: GAR
Dated: September 2, 2019
Received: September 4, 2019

Dear Akiko Dohi:

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,

For Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K192420

Device Name
CROWNJUN Nylon Suture

Indications for Use *(Describe)*
CROWNJUN Nylon Suture is intended to join the edges of soft-tissue wound or incision to ligate soft tissues.

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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510(K) Summary

Submission Date: 09/04/2019

K192420

SUBMITTER INFORMATION:

Company Name: Kono Seisakusho Co., Ltd.

Company Address: 3-43-16 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan

Contact Person: Hiroyuki Arai
Phone: +81-(0)3-3813-7411
harai@crownjun.co.jp

Device Trade Name: CROWNJUN Nylon Suture

Device Common Name: Suture, Nonabsorbable, Synthetic, Polyamide

Class: Class II

Classification: 21 CFR 878.5020
Nonabsorbable Polyamide Surgical Suture

Product Code: GAR

Predicate Devices: K151165, AESCULAP, INC. Dafilon Nonabsorbable Polyamide Surgical Suture.

Device Description:

The CROWNJUN Nylon Suture is a sterile nonabsorbable polyamide surgical suture. The CROWNJUN Nylon Suture is composed of long-chain aliphatic polymers polyamide 6,6 which is available undyed or dyed black using logwood extract (Hematein) per 21 CFR 73.1410. The CROWNJUN Nylon Suture is offered in diameters ranging from USP size 12-0 through USP 0 and available in various lengths from 2.5 cm to 90 cm with pre-attached needles. The needle is composed of 300 series stainless steel of various types of tip shapes, curvatures, and sizes. The product meets all requirements established by the United States Pharmacopeia (USP) for nonabsorbable surgical sutures.

Intended Use:

CROWNJUN Nylon Suture is intended to join the edges of soft-tissue wound or incision to ligate soft tissues.

Summary of Technological Characteristics:

The CROWNJUN Nylon Suture is a synthetic nonabsorbable monofilament sterile surgical suture as the predicate devices. It is available in black or undyed.
The proposed device has the same technological characteristics as its predicate device through comparison in product design, intended use, material composition, function, and range of sizes. The proposed device also has some differences in technological characteristics from those of the predicate device. These differences in the technological characteristics only reflect market strategy and/or perceived user preferences and do not impact substantial equivalence of the device.

Non-Clinical Tests Performed:

Non-clinical testing was conducted on The CROWNJUN Nylon Suture per FDA's Special Control Guidance Document: Surgical Sutures, to prove conformance to the requirements of USP for synthetic nonabsorbable suture, and biocompatibility testing in accordance to ISO 10993-1 to further demonstrate substantial equivalence to the predicate device. Biocompatibility testing within this submission includes the following: Cytotoxicity, Sensitization, Intracutaneous Irritation, Systemic and Muscle Implantation (12-week), Genotoxicity, Subchronic System Toxicity, Hemolysis, and Pyrogenicity. Physical properties and functionality testing assured that the device conformed with suture diameter and suture length, extractable color and sterility to methods outlined in USP.

Substantial Equivalence:

Comparison Items	New Device	Predicate Device
510 (k)	K192420	K151165
Product Code	GAR	GAR
Product Name	CROWNJUN Nylon Suture	Dafilon Nonabsorbable Polyamide Surgical Suture
Labeling	Sterile, Single Use, Nonabsorbable Suture	Sterile, Single Use, Nonabsorbable Suture
Indication for Use	CROWNJUN Nylon Suture is intended to join the edges of soft-tissue wound or incision to ligate soft tissues.	Dafilon Nonabsorbable Polyamide Surgical Sutures are indicated for use in all types of general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery and neurological procedures.
Material	Polyamide 6,6	Polyamide 6 and/or polyamide 6,6

Dyed/Undyed	Un-dyed and Dyed	Un-dyed and Dyed
Structure	Monofilament	Monofilament
Size	USP 12-0, 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0 (various lengths)	USP 11/0 (0.1), 10/0 (0.2), 9/0 (0.3), 8/0 (0.4), 7/0 (0,5), 6/0 (0,7), 5/0 (1), 4/0 (1.5), 3/0 (2), 2/0 (3), 0 (3,5), 1 (4), 2 (5) , 3 (6), 5 (7) (various lengths)
Thread Length	2.5 cm – 90 cm	30 mm- 2500 mm
Needle	300 series stainless steel	300 or 400 series stainless steel
Sterilization	Ethylene Oxide (EO)	Gamma Irradiation or Ethylene Oxide (EO)
Standards	Suture Material meets or exceeds the performance requirements defined in: USP 41 <861> USP 41 <871> USP 41 <881> ISO 10993-1	Suture Material meets or exceeds the performance requirements defined in: USP 35 <861> USP 35 <871> USP 35 <881> ISO 10993-1

Clinical Tests Performed:

No clinical trials were conducted.

Conclusion:

The CROWNJUN Nylon Suture is substantially equivalent to the predicate device, Dafilon Nonabsorbable Polyamide Surgical Suture in indications for use, fundamental scientific technology, and technological characteristics. It has the same design being a sterile, flexible, monofilament nonabsorbable thread meeting all the requirements of the United States Pharmacopeia (USP). The selected nylon suture material also has established history of use in the surgical suture industry.

The biocompatibility data and the results of performance testing presented, demonstrate the substantial equivalence of the CROWNJUN Nylon Suture to that of the predicate device. It further demonstrates conformance with the USP, ISO 10993, and FDA Guidance for Surgical Suture 510(k).