DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 26, 2016

Noxilizer, Inc.
Ms. Mary Dadone
Vice President of Regulatory Affairs and Quality Assurance
800 West Baltimore Street, Suite 151
Baltimore, MD 21201

Re: K160501
Trade/Device Name: Noxilizer Surgical Ruler
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: Class I
Product Code: FTY
Dated: April 26, 2016
Received: April 26, 2016

Dear Ms. Mary Dadone:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
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Enclosure

INDICATIONS FOR USE

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)*
K160501

Device Name
Noxilizer Surgical Ruler

Indications for Use *(Describe)*
The Noxilizer Surgical Ruler is a sterile, single use, manual measurement device intended to be used in various general surgical procedures.

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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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

NOXILIZER™ *Room Temperature Sterilization with Nitrogen Dioxide*

510(k) Summary for the Noxilizer Surgical Ruler
K160501

Sponsor and 510(k) Owner

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Contact Person

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Date This Summary Was Prepared

May 18, 2016

Name of Device

Trade Name: Noxilizer Surgical Ruler
Common Name: Surgical Ruler
Regulation Name: Manual surgical instrument for general use (21 CFR 878.4800)
Regulatory Classification: Class I
Product Code: FTY

Predicate Devices

Richard Allan Surgical Ruler (K790660)
Devon Surgical Ruler (K790084)

Device Description

The Noxilizer Surgical Ruler is a 6” x ½” stainless steel surgical ruler with laser engraved markings in both inches and centimeters. The Noxilizer Surgical Ruler is a single-use, sterile device distributed in individuals packages.

Indications for Use

The Noxilizer Surgical Ruler is a sterile, single use, manual measurement device intended to be used in various general surgical procedures.

Comparison of Device Characteristics

Characteristic	Noxilizer Surgical Ruler	Richard Allan Surgical Ruler	Devon Surgical Ruler
510(k) Number	K160501	K790660	K790084
Product Code	FTY	FTY	FZZ (sold as part of a marking kit)
Intended Use	Measurement in the Surgical Suite	Measurement in the Surgical Suite	Measurement in the Surgical Suite
Length	6 inches/150 mm	6 inches/150 mm	6 inches/150 mm
Sold Sterile	Yes	Optional (per current advertising)	Optional (per current advertising)
Method of Sterilization	Nitrogen Dioxide	Unknown	Unknown
Single Use	Yes	Yes (currently)	Yes (currently)

The Noxilizer Surgical Ruler differs from the predicates in the materials of construction (stainless steel rather than plastics) and the method of sterilization (nitrogen dioxide sterilization)

Shelf-Life

The Noxilizer Surgical Ruler shelf life of claim of six (6) months has been validated using accelerated aging results. The samples used for the shelf life studies were exposed to a worst-case cycle with the sterilant dose at the upper end of the tolerance limit, high-humidity, elevated temperatures, and extended sterilant dwell times. Accelerated aging was performed in a validated aging chamber per the Q10 Theory and ASTM F1980-07 (2011). The samples were aged at a test temperature of 55°C (±2°C) for 20 days, equivalent to an accelerated aging time of 39.7 days per year with an aging factor (Q_{10}) of 2.0. Sterile barrier properties were evaluated by visual inspection of the pouch package system, tensile testing of the seal, and bubble leak testing.

Visual inspection was performed per ASTM F1886 methods. All post-aging samples were visually inspected, passed the visual inspection, and did not show any sign of the sterile barrier being compromised.

Tensile testing of the seal was performed per ASTM F88 methods using the peak, 180° supported tail method. Both the applied seal and the chevron end of the pouch were tested.

The sample size was sufficient for a 95% confidence interval, 95% reliability. The acceptance criteria was as follows:

Accept if (sample mean) – $k_1 s \geq 1.0$ pound per linear inch (PLI), otherwise reject.
Where:
s = Sample standard deviation
k_1 = 2.566 (k value for 1-sided tolerance limits corresponding to the applicable sample size, confidence, and reliability requirements)

All samples had a tensile test value of 2.59 PLI or greater, and the test results exceeded the acceptance criteria.

Bubble leak testing was performed per ASTM F2096 methods. The sample size was sufficient for a 90% confidence interval, 95% reliability. All samples tested (less control samples) passed bubble leak testing (no streams of bubbles were detected).

Post-aging sterility testing was performed using intact samples incubated for 14 days in SCD media at 28ºC to 32ºC (mesophilic range, corresponding to bioburden test results). All samples were negative for growth at the end of the incubation period.

Biocompatibility

The Noxilizer Surgical Ruler may come into either direct or indirect contact with patients' intact skin. That is, it is possible that a surgeon would lay the ruler on intact skin, and it is also possible that the surgeon would touch the ruler and then touch the patient's skin.

- The duration of contact is less than 24 hours
- The site of contact is intact skin only

Therefore, per the Agency's most recent published draft guidance concerning selection of biocompatibility tests[1] and the recommendations of ISO 10993-1:2009, the following biocompatibility testing was performed:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity

[1] Use of International Standard ISO- 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" – Draft Guidance for Industry and Food and Drug Administration Staff, issued on April 23, 2013

The rulers used as the test articles for the biocompatibility tests were manufactured in accordance with the specified manufacturing process. The rulers were then exposed to a high-end worst-case, full-cycle session, where the sterilant dose, the humid air set point pressure, the dwell time, and the temperature were all manipulated to result in exposures at or above the higher limits specified in the sterilization process specification for the Noxilizer Surgical Ruler.

The exposed rulers were then evaluated by outside test houses under GLP conditions. Cytotoxicity testing was performed in accordance with the requirements of ISO 10993-5:2009; sensitization and irritation testing were performed in accordance with the requirements of ISO 10993-10:2010. The biocompatibility test results are summarized below.

Cytotoxicity testing was performed under GLP conditions using ISO MEM elution and L-920 Mouse Fibroblast Cells. Extraction was performed in E-MEM+ 5% FBS. The test article was incubated in the extraction vehicle for 24 ± 2 hours at 37 ± 1 ºC in a humidified atmosphere of 5 ± 1% CO_2 in air. There was no biological reactivity (Grade 0) of the cells exposed to the test article extracts. The response obtained from the positive and negative control article extracts confirmed the suitability of the test system. Based on the criteria of the protocol and the ISO 10993-5 guidelines, the test article meets the requirements of the test and is not considered to have a cytotoxic effect.

Sensitization testing was performed under GLP conditions following the ISO Guinea Pig Maximization Sensitization Test with two extracts, one in NaCl and one in cottonseed oil. The test articles were incubated in the respective extraction vehicle for 72 ± 2 hours at 50 ± 2ºC. The USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) extracts of the test article, Ruler 6.0", 316 SSTL, elicited no reaction at the challenge (0% sensitization), following an induction phase. Therefore, as defined by the scoring system of Kligman, this is a Grade I reaction and the test article is classified as having weak allergenic potential. Based on the criteria of the protocol, a Grade I sensitization rate is not considered significant and the test article meets the requirements of the ISO 10993-10 guidelines.

Irritation testing was performed under GLP conditions following the ISO Intracutaneous Irritation Test method with two extracts, one in NaCl and one in soybean oil. The test articles were incubated in the respective extraction vehicle for 72 ± 2 hours at 50 ± 2ºC.
The USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) extracts of the test article, Ruler 6.0”, 316 SSTOL, were evaluated for their potential to produce irritation after intracutaneous injection in New Zealand White rabbits. The test article sites did not show a significantly greater biological reaction than the sites injected with the control article. Based on the protocol, the test article meets the requirements of the ISO 10993-10 guidelines.

Conclusion: No new issues of safety or effectiveness have been raised, based on the nonclinical tests performed. The performance testing data for the subject device, Noxilizer Surgical Ruler demonstrates

that the subject device is as safe, as effective and performs as well as the legally marketed predicate devices.