July 16, 2019

SurGenTec, LLC
% Stephen Inglese
Founder/CEO
Quality Solutions and Support, LLC
PO Box 8271
Holland, Michigan 49422

Re: K190163
Trade/Device Name: ALARA Neuro Access Kit
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ
Dated: June 13, 2019
Received: June 17, 2019

Dear Stephen Inglese:

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

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K190163

Device Name
ALARA Neuro Access Kit

Indications for Use *(Describe)*
The ALARA Neuro Access Kit is indicated for pedicle pilot hole preparation, locating, and identifying spinal roots / nerves by providing proximity feedback.

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

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the ALARA Neuro Access Kit is provided below.

Device Common Name:	Nerve Stimulator / Locator
Classification Name:	Neurosurgical Nerve Locator
Device Proprietary Name:	ALARA Neuro Access Kit
Submitter:	SurGenTec, LLC 7601 N Federal Hwy, Suite 150A Boca Raton, FL 33487 561-990-7882
Contact:	Stephen W Inglese CEO, Founder Quality Solutions and Support, LLC Phone: 561-251-0876 Email: swi@qss-llc.com
Date Prepared:	July 15, 2019
Classification Regulation:	21 CFR § 874.1820, Class II
Panel:	Neurology
Product Code:	PDQ

Predicate Device: -

510k	Product Name	Clearance Date
K171807	ES2 Neuromonitoring Accessory Instruments	July 18,2017

Indication for Use:

The ALARA Neuro Access Kit is indicated for pedicle pilot hole preparation, locating, and identifying spinal roots / nerves by providing proximity feedback.

Device Description:

The ALARA Neuro Access Kit with Access Needle, Sheath and Extension Handle is a single – use: sterile stimulating electrode is manufactured with the following materials: 316 and LVM Stainless Steel, IXEF 1022/9008 and Lustram ABS. The disposable ALARA Neuro Access Kit is an Access Needle insulated with a sheath (**see figure 1**). The sheath is full length except for the distal tip (either a diamond or bevel tip) which provides tissue stimulation. The needle

utilizes an extension handle as an accessory (**see figure 2**) to provide the surgeon stability in placement of the access needle and by providing support by allowing for more working space during a surgical procedure.

The device is kitted with a set of individually packaged and (single use) disposable Alligator Clips (Rhythmlink International Alligator Clip RLSP487) see **figure 3**. The device registered with Rhythmlink (FDA registered FEI: 3003831320).

Figure 1- ALARA Access Needle with Sheath

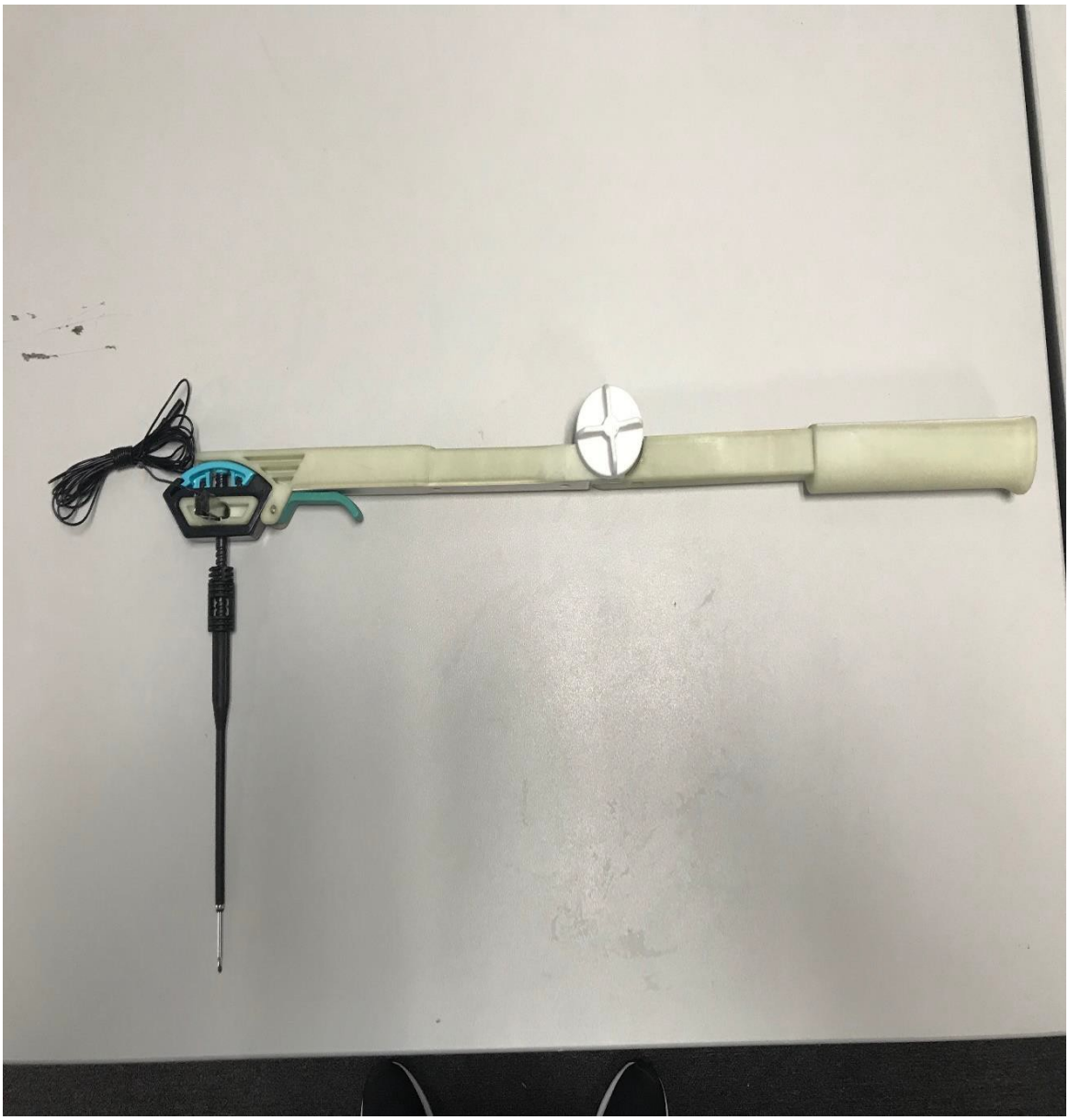

Figure 2- Extension Handle attached to the Access Needle

Figure 3- Access Needle with Extension Handle and Alligator Clip Attached / Packaged

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Performance Testing:

Bench testing was performed with the device in simulated use cases to determine that the device met its performance specifications. Where applicable, functionality testing included materials that simulate relevant mechanical properties of bone.

- ALARA Cannula Handle Torque Test - The cannula handle meets all acceptance criteria since the torque required to cause the cannula to fail as over twice the required torque of 25 in-lbs.

- ALARA Cannula Handle Pull Test - The cannula handle meets all acceptance criteria since the force required to cause the cannula to fail as over the required force of 60 lbf.

- ALARA Stylet Handle Pull Test - The stylet handle meets all acceptance criteria since the force required to cause the stylet to fail as over the required force of 60 lbf.

- ALARA Bevel Sheath Needle Functionality Test - The bevel sheath needle and extension handle meets all acceptance criteria since the samples were able to functionally perform the test without failure.

- ALARA Diamond Sheath Needle Functionality Test - The diamond sheath needle and extension handle meets all acceptance criteria since the samples were able to functionally perform the test without failure.

- Electrical Safety - IEC 60601-1 Edition 3.1, with AAMI/CSA/EN Deviations: Leakage Current Test: (Clause 8.7), Dielectric Voltage Withstand: (Clause 8.8.3), Humidity Preconditioning Treatment: (Clause 5.7), Enclosure Mechanical Strength: (Clause 15.3), Drop Test: (Clause 15.3.4), Ball Pressure: (Clause 8.8.4.1), Patient Leads and Cables: (Clause 8.5.2.3). SUMMARY**:** The limited evaluation and testing of the ALARA 11 Gauge Access Needle with Sheath, found the sample(s) to be in compliance with the above specified standards.

Substantial Equivalence:

Based on similar intended use and technological characteristics, the ALARA Neuro Access Kit is Substantially equivalent to the predict device; K171807 – ES2 Neuromonitoring Accessory Instruments **Table 1** demonstrates the technological features; both similar and different.

Table 1: Device Comparison Table for Substantial Equivalence

Administrative Characteristic	**Subject Device**	**Predicate Device**
	SurGenTec, LLC – K190163	**Stryker – K171807**
Device Name	**ALARA Neuro Access Kit**	**ES2 Neuromonitoring Accessory Instruments – 200, 300 and 400 LITe Y-Needles**
Regulation	21 CFR § 874.1820, Class II	21 CFR § 874.1820, Class II
Product Code	PDQ	PDQ
Device Characteristic:		
Indications For Use	**The ALARA Neuro Access Kit is indicated for pedicle pilot hole preparation, locating, and identifying spinal roots / nerves by providing proximity feedback.**	**The ES2 Neuromonitoring instruments (Awls, Taps, Screwdriver and LITe Y-NEEDLE 200, 300 and 400) can be used by the surgeon to assist in location of the spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws in open and percutaneous minimally invasive posterior surgical approaches of the non-cervical spine.**
Material	Surgical Stainless Steel, lxef® 1022/9008 and Acrylonitrile Butadiene Styrene (ABS)	Surgical Stainless Steel and Acrylonitrile Butadiene Styrene (ABS)
IEC 60601 Compliant	Yes	Yes
Use of the Needle	Needle depth stop	Needle depth stop
Sterility	**Sterile (gamma)**	**Sterile and Non Sterile** **Non-sterile devices are provided with validated steam sterilization parameters to assure an SAL of 10^{-6}**
Reusable /Single Use	**Single Use**	**200, 300, and 400 LITe Y Needles – Single Use** **Awls, Taps, and Screwdrivers - Reusable**
Connection to a Neuromonitoring Unit	Wire and Clip	Wire and Clip
Extension Handle	**Yes**	**No**

Instrument Type (Description)	**ALARA Needle, Handle**	**Awl, Taps, Screwdrivers, Guidewires (K-wires) and 200,300, 400 LITE Y-Needles**
Biocompatibility Patient Contact Duration	Limited patient duration contact (≤24 hours)	Limited patient duration contact (≤24 hours)
Biocompatibility	Yes	Yes
Surgical Approach	Open or Percutaneous/ Minimally Invasive	Open or Percutaneous/ Minimally Invasive
Compatible with Common Neuromonitoring Consoles & Software	Yes	Yes
Connection to Neuromonitoring Unit	**Clip**	**Clip or Probe (based on Neuromonitoring system)**

*Bold text denotes a difference between the subject device and the predicate device.

Summary of Substantial Equivalence:

As described above, the difference in technological characteristics do not raise new types of safety and effectiveness issues. The testing data (biocompatibility, bench testing and electrical safety) provided in this 510(k) show equivalence to the predicate as cleared in K171807 and therefore the ALARA Neuro Access Kit can be found substantially equivalent to the predicate device.