April 24, 2025

SurGenTec LLC
Guilherme Pires
Vice President of Operations
911 Clint Moore Rd
Boca Raton, Florida 33487

Re: K243945
Trade/Device Name: ALARA BMA Neuro Access Kit (ALARA BMAN and ALARA BMAC Kit)
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW, PDQ
Dated: February 20, 2025
Received: February 20, 2025

Dear Guilherme Pires:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica Carr -S

Jessica Carr, PhD
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K243945

Please provide the device trade name(s).

ALARA BMA Neuro Access Kit (ALARA BMAN and ALARA BMAC Kit)

Please provide your Indications for Use below.

The ALARA BMA Neuro Access Kit (ALARA BMAN and ALARA BMAC Kit) is indicated for aspiration of bone marrow or autologous blood.

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

The ALARA BMAC Needle is intended for use in harvesting core biopsy samples of cancellous bone and/or bone marrow.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Submitter: SurGenTec, LLC
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Phone: 561-990-7882
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Official Correspondent: Mr. Guilherme Pires
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Date Prepared: April 24, 2025

Trade Name: ALARA BMA Neuro Access Kit (ALARA BMAN and ALARA BMAC Kit)

Common Name: Aspiration Needle, BMA Needle

Classification: 21 CFR 876.1075, 21 CFR 874.1820

Product Code: KNW, PDQ

Predicate Device: ALARA Neuro Access Kit (K240664)
ALARA Neuro Access Kit (K190163)
Ranfac Bone Marrow Aspiration Needle (K131157)

Reference Device: Avitus Bone Harvester (K170539)

Device Description:
The ALARA BMA Neuro Access Kit utilizes a neuromonitoring platform in providing the surgeon with nerve / root location feedback during the approach to a pedicle to support a guidewire placement.

The ALARA BMAN and ALARA BMAC Kit includes various single-use needles designed for bone marrow aspiration and aspiration of autologous blood.

Indications for Use:
The ALARA BMA Neuro Access Kit (ALARA BMAN and ALARA BMAC Kit) is indicated for aspiration of bone marrow or autologous blood.

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

The ALARA BMAC Needle is intended for use in harvesting core biopsy samples of cancellous bone and/or bone marrow.

Substantial Equivalence:
The ALARA BMA Neuro Access Kit (ALARA BMAN and ALARA BMAC Kit) is substantially equivalent to the predicate device.

Information	Subject Device	Primary Predicate	Secondary Predicate	Reference Device
Trade Name	**ALARA BMA Neuro Access Kit (ALARA BMAN and ALARA BMAC Kit) SurGenTec, LLC**	**Ranfac Bone Marrow Aspiration Needle Ranfac Corporation**	**ALARA Neuro Access Kit SurGenTec, LLC**	**Avitus Bone Harvester**
510(k) Number	Subject Device	K131157	K190163	K170539
Regulation	21 CFR 876.1075 21 CFR 874.1820	21 CFR 876.1075	21 CFR 874.1820	21 CFR 876.1075
Classification	II	II	II	II
Product Code	PDQ, KNW	KNW	PDQ	KNW
Indications for Use	The ALARA BMA Neuro Access Kit is indicated for pedicle pilot hole preparation, locating, and identifying spinal roots / nerves by providing proximity feedback. The ALARA BMA Neuro Access Kit (ALARA BMAN and ALARA BMAC Kit) is indicated for aspiration of bone marrow or autologous blood. The ALARA BMAC Needle is intended for use in harvesting core biopsy samples of cancellous bone and/or bone marrow.	The Ranfac Bone Marrow Aspiration Needle is intended for use in aspirating bone marrow	The ALARA Neuro Access Kit is indicated for pedicle pilot hole preparation, locating, and identifying spinal roots / nerves by providing proximity feedback.	The Avitus Bone Harvester is intended to harvest cancellous bone and marrow.
Surgical Approach	Minimally Invasive	Minimally Invasive	Minimally Invasive	Minimally Invasive
Material	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Diameter	11 Gauge – 3mm	8 Gauge, 11 Gauge	11 Gauge – 3mm	N/A

Lengths	12.8cm	11cm – 15cm	12.8cm	N/A
Use of the Needle	Needle depth stop at bone	Needle depth stop at bone	Needle depth stop at bone	N/A
Packaged Sterilized	Yes	Yes	Yes	Yes
Single-Use Device	Yes	Yes	Yes	Yes

The ALARA BMAN and BMAC Kit are similar in materials and design to the predicate device. Both are manufactured from stainless steel and ABS. Both devices include a cannulated version and include similar lengths, and diameters. Both devices have plastic molded handles for the cannula and stylet that mate with each other to prevent separation.

Performance Testing:

The following tests have been performed on the ALARA BMA Neuro Access Kit (ALARA BMAN and ALARA BMAC Kit):

- Cannula Handle Torque Test
- Cannula Handle Pull Test
- Stylet Handle Pull Test
- Needle Strength from Impaction and Compression Tests
- Luer Lock Verification per ISO 80369
- Needle Particle Aspiration
- Needle Cell Viability Test
- Packaging Validation
- Sterilization Validation
- Biocompatibility Assessment

Conclusion:

Based on the similarities in materials, design, principles of operation, and results of the non-clinical testing, the ALARA BMA Neuro Access Kit (ALARA BMAN and ALARA BMAC Kit) is substantially equivalent to the predicate device for the requested indications for use.