April 23, 2021

Arbutus Medical Inc.
Mr. Michael Cancilla
Director, Engineering & Partnerships
828 10th Ave W, Suite 560
Vancouver, British Columbia V5Z 1L8
Canada

Re: K203605
Trade/Device Name: SteriTrak™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: JEC
Dated: March 26, 2021
Received: April 1, 2021

Dear Mr. Cancilla:

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,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*

K203605

Device Name
SteriTrak

Indications for Use *(Describe)*

SteriTrak is indicated for implantation through the skin and bone so that traction may be applied to the skeletal system.

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

510(k) Applicant: Arbutus Medical Inc.
828 10th Ave W, Suite 560
Vancouver, British Columbia
Canada, V5Z 1L8

Primary Contact: Michael Cancilla
Director, Engineering & Partnerships
Mobile: +1 778 773 6477
michael.cancilla@arbutusmedical.ca

Date Prepared: November 30, 2020

Device Trade Name: SteriTrak™

Device Common Name: Skeletal Traction Pin

Device Classification Name: Smooth or Threaded Metallic Bone Fixation Fastener

Regulation Number: 888.3040

Product Code: JEC (Component, Traction, Invasive)

Classification: II

Panel: Orthopedic

Primary Predicate Device: K960385 – Sterile Kirschner Wires and Steinmann Pins

Predicate Device: K761088 – Modified Skeletal Traction Pin

Device Description: SteriTrak™ is a sterile, temporarily implantable Kirschner wire (K-wire). SteriTrak™ is intended to be implanted into the bone for the purposes of providing an anchor for skeletal traction. SteriTrak™ is intended to be inserted while the patient is in the Emergency Room, prior to admittance to the Operating Room for surgery. When the patient is transferred to the Operating Room for surgery, skeletal traction is released and SteriTrak™ is removed.

The SteriTrak™ surgical grade 316L stainless steel pin is implantable up to 30 days. SteriTrak™ is provided with a guiding handle intended to be used as a pin stabilizing holder for the orthopedic surgeon.

Indications for Use: SteriTrak™ is indicated for implantation through the skin and bone so that traction may be applied to the skeletal system.

Substantial Equivalence: The indicated use, design and technological characteristics for SteriTrak™ are the same as the predicate devices. The intended use for SteriTrak™ is identical to the primary predicate device. The applied part of the SteriTrak™, the stainless steel K-wire, is exactly the same as the primary predicate device. Human factors and usability testing demonstrates that the polycarbonate guide is effective in stabilizing the SteriTrak™ implantable pin during insertion and does not raise any concerns regarding the safe and effective use of SteriTrak™.

Performance Testing: Non-clinical testing of SteriTrak™ in support of this submission included the following activities:

- Biocompatibility assessment to ISO 10993-1
- Usability testing to IEC 62366-1
- Pin torque transfer to ASTM F-138-19 and ISO 5832-1
- Label legibility testing to ISO 14630:2012

These activities demonstrate that SteriTrak™ is substantially equivalent to the predicate devices.