May 18, 2018

Summit Medical Ltd.
Robyn Cochrane
RA Executive - Projects
Industrial Park
Bourton on the Water
Gloucestershire
GL54 2HQ
United Kingdom

Re: K173110
Trade/Device Name: Graftsite Local Anesthetic Delivery Assistance Device
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: April 2, 2018
Received: April 2, 2018

Dear Robyn Cochrane:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K173110

Device Name
GRAFTSITE Local Anesthetic Delivery Assistance Device

Indications for Use *(Describe)*
Assistance in the delivery of local anaesthetic after hamstring harvest during ligament reconstruction 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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Name of device	GRAFTSITE Local Anesthetic Delivery Assistance Device
Classification	Classification – II Product Code – BSP Classification name – Anesthesia conduction needle Classification Rule – 868.5150 Device Panel – 73 - "Anesthesiology"
Predicate device(s)	Pajunk® "Unipolar Needles", initially cleared under K000722 and subsequently cleared under part of Special 510(k) K053283 (under new trade name UniPlex NanoLine cannula).
Indications for use	GRAFTSITE Indications for Use Statement - "Assistance in the delivery of local anaesthetic after hamstring harvest during ligament reconstruction procedures." The Indications for Use statement of GRAFTSITE is different to that of the predicate device - "The PAJUNK needles are used to puncture the tissue in order to gain entry and locally inject anesthetics to induce regional anesthesia. An electrical stimulus may be applied to the needle via a cable and connector to assist the physician pinpoint the area of application." due to GRAFTSITE having a more limited depiction of use compared to that of the predicate. GRAFTSITE has a catheter round and blocked at the patient end as is not required to puncture tissue to gain entry, due to the

	method of access being through the already present femoral gutter, compared to the predicate that requires a puncturing tip at the end of the cannula in order to pierce the skin for nerve access. Therefore, this difference does not raise different questions of safety and effectiveness. GRAFTSITE is used for inducing regional anesthesia by assisting in the injection of anesthetics like the predicate, it just has a more limited depiction of use to only after hamstring harvest during ligament reconstruction procedures. In subsequent clearance K053283 it states that PAJUNK Unipolar needles (initially cleared under K000722) are marketed as single shot needles under the trade name UniPlex and that the anesthesia conduction catheter allows for bolus injections or continuous infusion of local anesthetics. This shows the predicate can be used for the same intended purpose as GRAFTSITE, assisting in delivery of a bolus of anesthetic, therefore this does not raise different questions of safety or effectiveness. GRAFTSITE does not require the physician to pinpoint the area of application via electrical stimulus, as it fulfils its intended use through localization of anesthetic directly to nerve endings within, and surrounding, the comorbidities at the already femoral gutter, compared to the predicate which utilizes nerve stimulation to localize the more proximal nerve sheath. Therefore, this difference does not raise different questions of safety and effectiveness.
Device description	GRAFTSITE is 28.25 cm in length with an inner diameter of 2.6 mm and an outer diameter of 4.0 mm, sized to fit down the hamstring harvest site. It is rounded and blocked at the patient end and has a 6% female luer at the user end. There are lateral eyes over a length at the patient end of the catheter. A buttoned stylet consisting of a rigid stainless steel rod of diameter slightly less than the bore of the catheter, functions to stiffen the device. GRAFTSITE can be used to directly administer a bolus of the users chosen local anesthetic, via injection down the lumen of the catheter, into the terminus of the gutter at the site of comorbidity.
Non-clinical testing	Based on the characteristics identified as relevant from performance standards, GRAFTSITE was directly compared to the predicate in comparative performance tests. Testing performed in order to verify substantial equivalence included;

	• Pressure testing of the catheter/hub for resistance to liquid leakage (in accordance with EN 1618 and ISO 594-2) • Tensile bond performance of the catheter/hub and stylet/button (in accordance with BS 6196 and EN 1618) • Corrosion resistance of the stylet (as per EN 1618) • Flow rate of the catheter (in accordance with EN 1618) • Radio-opacity of the catheter (in accordance with ASTM F640-12) • Human factors/usability validation of the device GRAFTSITE performed equally well in all performed tests necessary to demonstrate that it is substantially equivalent to the predicate. The catheter luer hub is manufactured in accordance with EN1707/ISO 594-2 and BS EN 20594-1/ISO 594-1. Further testing specific to ISO 594-1/ISO 594-2 was not required due to the following; • Gauging testing - no axial force applied during intended use • Air leakage during aspiration - no aspiration during intended use • Separation force - no axial force applied during intended use • Stress cracking - limited stress applied during intended duration of use (≤1 minute) • Unscrewing torque - no unscrewing torque applied during intended use • Ease of assembly - no axial or rotational force applied during intended use • Resistance to overriding - no torque applied during intended use In addition, the requirement for a compliant 6% luer syringe, in accordance with ISO 594-2, to be used in conjunction with the device is indicated to users in the IFU. Biocompatibility testing on the fully finished device demonstrated that GRAFTSITE is biocompatible in relation to its intended use in accordance with ISO 10993-1 and the FDA guidance document on that standard, and is therefore determined to be

	biocompatible within a risk management process. This test process included cytotoxicity, sensitization, irritation/ intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity, particulate analysis, hemolysis, and endotoxin testing. Gamma irradiation validation using the VDmax25 method, in accordance with ISO 11137-1 and ISO 11137-2, was successful in eliciting no growth for a routine processing dose of 25-40kGy and giving a SAL of 10^{-6} (in accordance with EN 556).
Clinical testing	Clinical data was not required to establish substantial equivalence between GRAFTSITE and the predicate device.
Physical differences	Both GRAFTSITE and the predicate are constructed of established, clinically used materials, with confirmatory biocompatibility testing verifying this. The catheter being rounded and blocked at the patient end is due to the method of access being through the already present femoral gutter, compared to the predicate that requires a puncturing tip at the end of the cannula in order to pierce the skin to access the femoral nerve. The length of the catheter is significantly longer due to the requirement for placement at the terminus of the proximal femoral gutter compared to the predicate, which typically only requires access 2 – 3cm below the skin. The stainless steel stylet assembly of GRAFTSITE provides rigidity to the catheter upon insertion compared to the predicate which has a rigid stainless steel cannula for insertion The presence of a stimulator cable with the predicate is due to the indications for use (i.e. for the localization of peripheral nerve bundles through nerve stimulation). GRAFTSITE is not indicated for peripheral nerve stimulation. Comparative *in vitro* testing was performed, with the results for GRAFTSITE compared to the predicate, which showed that there were no different questions of safety and effectiveness raised.
Handling differences	Whilst the predicate is of a clinically standard technique, GRAFTSITE was proven to be usable in a cadaveric usability investigation, and did not raise different questions of safety and effectiveness when compared to the predicate

Chemical differences	Both GRAFTSITE and the predicate are constructed of established, clinically used materials, with confirmatory biocompatibility testing verifying this. Comparative *in vitro* testing was performed, with the results for GRAFTSITE compared to the predicate.
Substantial equivalence	Based on the similarities in design, function, indications for use and fundamental scientific technology, the subject devices of this submission is similar to the predicate device and does not raise different questions of safety and effectiveness. Therefore, Summit Medical concludes that the subject device, GRAFTSITE, is substantially equivalent to the predicate device.