September 9, 2020

HK Surgical
Gary Mocnik
Official Correspondent
1271 Puerto del Sol
San Clemente, California 92673

Re: K193664
Trade/Device Name: SubQKath Catheter and Needle Set
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: Class II
Product Code: BSO
Dated: August 6, 2020
Received: August 10, 2020

Dear Gary Mocnik:

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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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)*

K193664

Device Name

SubQKath Catheter and Needle Kit

Indications for Use *(Describe)*

The SubQKath Catheter and Needle Kit is intended to provide continuous and/or intermittent infusion of local anesthetics and analgesics for subcutaneous infiltration local anesthesia, peripheral plexus anesthesia and pain management during pre-operative, perioperative and post-operative periods associated with 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**Section 4** **510(k) Summary**

**1. 510(k) Summary**

K193664

I. SUBMITTER

HK Surgical
1271 Puerto del Sol
San Clemente, CA 92673

Contact person: Gary Mocnik
Phone: (949) 433.0413
Date prepared: December 24, 2019

II. DEVICE
Trade name: SubQKath Catheter and Needle Set
Common name: Subcutaneous Catheter
Classification name: Anesthesia Conduction Catheter
Classification Regulation : 868.5120
Class: II
Product Code: BSO

III. PREDICATE DEVICE
PAINfusor Catheter (K111031)- primary predicate
This predicate has not been subject to a design-related recall
PAJUNK Wound Infiltration Catheter Kit (K080675)- reference predicate
This predicate has not been subject to a design-related recall

IV. DEVICE DESCRIPTION
The HK SubQKath Subcutaneous Catheter is a device intended to provide a means of delivery of local analgesics into the human body via a fenestrated catheter. The device is a single lumen catheter available in a single gauge (16g) size. The distal end of the device allows for flow of analgesia into the surgical wound. The device is supplied sterile and is intended for single use.

V. INDICATIONS FOR USE
The SubQKath Catheter and Needle Kit is intended to provide continuous and/or intermittent infusion of local anesthetics and analgesics for subcutaneous infiltration local anesthesia, peripheral plexus anesthesia and pain management during pre-operative, perioperative and post-operative

periods associated with surgical procedures.

The SubQKath Catheter and Needle Kit is intended for use in adult patients.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the SubQKath Catheter and Needle Kit are highly analogous to the predicate devices. The similarities and differences are illustrated in the table below:

| | **SubQKath Catheter and Needle Kit** | **PAINfusor Catheter (K111031) Primary Predicate** | **PAJUNK Wound Infiltration Catheter Kit (K080675)- Reference Predicate** |
|---|---|---|---|
| **Principle of Operation** | Insertion of catheter at or near the surgical site and infusion of analgesia/ anesthetics | SAME | SAME |
| **Patient population** | Adults | SAME | SAME |
| **Catheter placement technique** | Over-the-needle | SAME | SAME |
| **Materials** | Medical grade polymers, metals | SAME | SAME |
| **Catheter Diameter (OD)** | 16G | 19G | 19G |
| **Catheter Length** | 5.67” (14.40 cm) | 37.5cm<br>42.5cm<br>50cm<br>57.5cm<br>65cm | 420mm<br>500mm<br>600mm<br>700mm<br>900mm |
| **Tip type** | Fenestrated | | SAME |
| **Fenestration length** | (length of fenestration, 4.3-4.5 inches number of holes, 11 diameter of holes 0.040”) | Fenestration length:<br>2.5cm<br>7.5cm<br>15cm<br>22.5cm<br>30cm | Fenestration length:<br>25mm-300mm |
| **Placement duration** | Up to 72 hours | | |
| **Needle Configuration** | Straight length gauge: | Straight | Straight |
| **Luer engagement** | Yes | SAME | SAME |

| | SubQKath Catheter and Needle Kit | PAINfusor Catheter (K111031) Primary Predicate | PAJUNK Wound Infiltration Catheter Kit (K080675)- Reference Predicate |
|---|---|---|---|
| **Flow Rate** | Flow rate is dependent on the infiltration pump used and the associated flow rates. The differences in fenestration pattern did not affect flow characteristics, as demonstrated by flow performance testing. | Flow rate is dependent on the infiltration pump used and the associated flow rates. Fenestration features do not affect flow characteristics as demonstrated by flow performance testing | Flow rate is dependent on the infiltration pump used and the associated flow rates. Fenestration features do not affect flow characteristics as demonstrated by flow performance testing |
| **Components of Device Kit** | • Catheter<br>• Needle introducer | • Catheter<br>• Needle introducer<br>• Dressing | • Infiltration Catheter<br>• Puncture cannula (needle)<br>• Filter<br>• Syringe<br>• Pump |
| **How provided** | Sterile, single use | Sterile, single use | Sterile, single use |

VII. PERFORMANCE DATA

The following performance data were evaluated in support of the substantial equivalence.

- Physical Properties Verification
- Bond and Material Strength Verification
- Needle quality
  - Sharpness after one-year aging
  - Stiffness after one-year aging (ISO 9626)
- Kink resistance
- Flow rate characterization
- Liquid leakage
- Functional Verification
- Biocompatibility

The indwelling Sub Q Kath catheter portion of the HK Surgical SubQKATH device is considered to fall under the guidelines for an externally communicating device with direct tissue/bone contact for a prolonged patient contact duration (> 24 hours to 30 days per the ISO guideline and typically a maximum exposure of 48 hours in the actual

clinical application) as defined by the International Organization for Standardization (ISO) 10993-1:2018 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and U.S. Food and Drug Administration (FDA) *Guidance Document for the Use of ISO 10993-1 (issued 06/16/2016)* guidelines. The aspects of biocompatibility for consideration as suggested by the ISO 10993-1 and FDA guidelines were follows in Table 2.

**Biocompatibility tests conducted**

- Cytotoxicity
- Intracutaneous Irritation
- Implantation
- Sensitization
- Systemic Toxicity
- Genotoxicity

In summary, the HK Surgical Sub Q Kath device was evaluated with a test battery addressing the suggested aspects of biocompatibility as suggested in the ISO 10993-1:2018 guidelines.

- Sterilization Validation

A protocol was successfully executed to establish the procedures for validation of an ethylene oxide sterilization process to a 10·6 sterility assurance level (SAL). Performance qualifications was executed using the overkill approach as referenced in the international standard, ANSI/AAMI/ISO 11135.

- Sterile Barrier Performance

Testing was successfully executed to demonstrate compliance with applicable elements of ISO 11607.

The subject device met the acceptance criteria of the above tests, and did not raise new questions of safety and effectiveness.

## VIII. CONCLUSIONS

The non-clinical testing performed for the SubQKath Catheter and Needle Kit demonstrated that the performance of the device is equivalent to the legally marketed predicate devices.
In summary, the SubQKath Catheter and Needle Kit has the same intended use as the proposed predicate and difference in technological features do not raise different questions of safety and effectiveness.