Interrad Medical Inc
% Denise Lenz
Regulatory Consultant
Libra Medical, Inc
8401 73rd Ave North, Suite 63
Brooklyn Park, Minnesota 55428

Re: K210629
Trade/Device Name: SecurAcath
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: OKC, KMK
Dated: February 19, 2021
Received: March 2, 2021

Dear Denise Lenz:

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,

James M.
Simpson Jr -S7

for Payal Patel
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210629

Device Name
SecurAcath

Indications for Use *(Describe)*
The SecurAcath Device is indicated for catheter securement to the access site by means of subcutaneous anchors in:
a) Short or long-term securement of percutaneous indwelling catheters for intravenous use
b) Short and long-term securement of percutaneous indwelling catheter for abscess/general drainage

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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8 510(K) SUMMARY

8.1 ADMINISTRATIVE INFORMATION

Date of Summary Preparation: **February 19, 2021**

8.1.1 Contact Information

Submitter/Manufacturer

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8.1.2 Device Information

Trade Name	SecurAcath
Common Name	Subcutaneous securement device or Subcutaneous Engineered Stabilization Device
Classification Name	Implanted Subcutaneous Securement Catheter
Classification Regulation	21 CFR 880.5970/880.5210/878.4200
Class	Class II
Panel	General Hospital
Product Code	OKC / KMK

8.2 PREDICATE DEVICE

The modified device is substantially equivalent to the Interrad Medical SecurAcath (K180994).

8.3 DEVICE DESCRIPTION

The SecurAcath device is a standalone subcutaneous anchoring securement system used to secure the catheter to the access site. The securement is achieved by means of a blunt nitinol anchor deployed into the subcutaneous space at the catheter access site, and the clamping of the catheter shaft between the Base Assembly and Cover of the device.

8.4 INTENDED USE

The SecurAcath device is intended to secure catheters by means of a subcutaneous anchor.

8.5 INDICATIONS FOR USE

The SecurAcath Device is indicated for catheter securement to the access site by means of subcutaneous anchors in:

a) Short or long-term securement of percutaneous indwelling catheters for intravenous use
b) Short and long-term securement of percutaneous indwelling catheter for abscess/general drainage

8.6 TECHNOLOGICAL CHARACTERISTICS

The SecurAcath is a single use, sterile device for securing indwelling catheters. The device is a stand-alone accessory to percutaneous indwelling catheters. The securement to the catheter access site is achieved by means of a blunt nitinol Anchor deployed into the subcutaneous space at the catheter access site. The securement of the catheter is achieved by the clamping of the catheter shaft between the Base Assembly and Cover of the device. This reduces catheter migration and accidental pull-out while not significantly affecting fluid flow. The SecurAcath has the same technological characteristics as the predicate device beside the predicate device is pad printed and does not contain the laser marking additive in the polypropylene portion to optimize the laser marking of the device (K180994).

8.7 DEVICE COMPARISON

Table 8-1: Comparison of Device Characteristics to Marketed Predicate Device

Items	Predicate SecurAcath (K180994)	SecurAcath (Current Device)
Product Name	Interrad Medical SecurAcath	Same-No change
Intended Use	The SecurAcath device is intended to secure catheters by means of a subcutaneous anchor.	Same - No change
Indication for Use	The SecurAcath Device is indicated for catheter securement to the access site by means of subcutaneous anchors in: a) Short or long-term securement of percutaneous indwelling catheters for intravenous use b) Short and long-term securement of percutaneous indwelling catheter for abscess/general drainage	Same - No change

Regulation Number and Product Code	21 CFR 880.5970 21 CFR 880.5210 21 CFR 878.4200 OKC/KMK	Same - No change
Classification	Class II	Same - No change
Regulatory Classification Name	Device, Vascular and Non-Vascular Catheter Securement	Same - No change
Technological Characteristics	Single use, sterile device for securing indwelling catheters. The device is a stand-alone accessory to percutaneous indwelling catheters and consists of a subcutaneous nitinol anchor that is deployed in the subcutaneous space at the catheter access site to reduce catheter migration and pull-out.	Same - No change
Technology-Materials	• PP Mevopur/Compound 100% SG702 Poppy V2 (first shot material) • TPE Mevopur/Counpound 100% G2706SLRBL V2 (second shot material) • Nitinol (anchor) • Marabu TPR 980 (Black ink)	• PP Mevopur-Orange/Compound 100% SG702 (first shot material) with laser marking additive. Material passed ISO 10993, design verification and shelf life testing and does not impact safety and effectiveness. • TPE Mevopur/Compound 100% G2706SLRBL V2 (second shot material)- Same, no change. • Nitinol with/without premium surface finish (anchor). Material passed ISO 10993 and design verification testing and the change does not impact safety and effectiveness.
Dressing Compatibility	Compatible with standard adhesive dressing including Biopatch and Tegaderm.	Same - No change
Cleaning solution compatibility	Compatible with standard skin cleaning solution including Chlorhexidine, alcohol, and iodine solution.	Same - No change
Principles of Operation	Catheter shaft held between the Base and Cap of the SecurAcath with nitinol anchors extending into the subcutaneous space from the base.	Same - No change
Use duration	For the life of the catheter secured unless anchors get accidently pulled out.	Same - No change
MRI Compatibility	MR Conditional	Same - No change
Device Configuration	Single use, sterile device	Same - No change
Packaging Configuration	1) Device on a backercard and an Extension Tube Tag inside a Tyvek pouch. Ten devices in Tyvek Pouch and ten Patient Guide Cards inside the 10-up shelf box.	1) Device in a Tyvek pouch. 10 devices in Tyvek Pouch inside the 10-up shelf box. Patient Guide Cards available upon request. New packaging configuration

	2) Tyvek pouch contains anti-block additive (CAS number 7631-86-9) in the nylon.	passed ISTA 2A, ASTM D4169, sterile barrier performance testing and ISO 10993-7 testing and the new packaging configuration does not impact safety and effectiveness. 2) Tyvek pouch contains anti-block additive (CAS number 1344-01-0) in the nylon. Tyvek pouch supplier data for sterilization validation and shelf life were evaluated and pouch sealing process validation testing passed. The anti-block additive in the nylon layer does not impact safety and effectiveness.
Labeling Configuration	1) Extension Tube Tag included in Tyvek pouch. 2) Label content on device applied as an ink. 3) Labeling on Pouch and Shelf Box.	1) Extension Tube Tag available upon request. New packaging configuration passed ISTA 2A, ASTM D4169, sterile barrier performance testing and ISO 10993-7 testing. The new packaging configuration does not impact safety and effectiveness. 2) Label content on device applied as a laser marking. Laser marking passed testing per IEC 60601-1 for durability of markings and the laser marking does not impact safety and effectiveness. 3) Labeling on Pouch and Shelf Box-Same, no change.
Shelf Life	Shelf life of 2 years.	Shelf life of 4 years. Shelf life product was 2X sterilized, passed design verification testing including pouch seal peel and bubble leak tests. The extension of the shelf life does not impact safety and effectiveness.
Size	3F, 4F, 5F, 6F, 7F, 8F, 10F, 12F	Same - No change
Biocompatibility	Meets ISO 10993-1	Same - No change
Sterilization method and sterility	EtO and SAL of 10^{-6}	Same - No change

8.8 PERFORMANCE DATA

Performance tests include dimensional verification, functional tests and marking durability. The company performed testing to demonstrate that the device meets product specifications and is not negatively impacted by the material change or marking process change. The device uses a modified Polypropylene material formulation to optimize the device markings using a laser instead of pad printing the device markings. All other materials are the same as its predicate device. The device continues to meet the same specifications as its predicate devices. Test results demonstrate that the device functions as intended. The following tests were performed:

Dimensional

Joint Tensile Strength
Base & Cover Interaction
Hinge performance
Device Marking Durability

8.9 SUBSTANTIAL EQUIVALENCE

The SecurAcath device covered by this submission is substantially equivalent to the predicate Interrad Medical SecurAcath device K180994.

The Polypropylene material formulation change and change from pad printing to laser marking to the SecurAcath device results in the same indication for use, same principles of operation, same technological characteristics, incorporates the same design, and are packaged and sterilized using the same materials and processes as the previously cleared predicate device. The changes do not raise new questions of safety or efficacy.

8.10 CONCLUSION

Based on the test data, the same intended use, and same indications for use, the modified SecurAcath device is found to be substantially equivalent to its predicate.