July 9, 2019

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

Re: K180994
Trade/Device Name: SecurAcath (5F, 6F, 7F, 8F, 10F, 12F)
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: OKC, KMK
Dated: April 13, 2018
Received: April 16, 2018

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,

Long Chen, Ph.D.
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

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)*
K180994

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 or long-term securement of percutaneous indwelling catheters 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: July 8, 2019

8.1.1 Contact Information

Submitter/Manufacturer

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Primary Submission Contact

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8.1.2 Device Information

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

8.2 PREDICATE DEVICE

The SecurAcath is substantially equivalent to the following:

- K180769 Interrad Medical SecurAcath

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 (K180769)

8.7 PERFORMANCE DATA

Performance tests include dimensional verification, functional tests and securement reliability. The company performed testing to demonstrate that the device meets product specifications and is able to secure catheters to access sites. The device uses the same material as its predicate device and meets the same specifications as its predicate devices. Test results demonstrate that the device functions as intended. The following tests were performed:

Dimensional
Base & Cover Interaction
Catheter Securement Performance
Catheter Interaction
Human Factor
Design Validation

8.8 SUBSTANTIAL EQUIVALENCE

The SecurAcath device covered by this submission is substantially equivalent to the predicate Interrad Medical SecurAcath device K180769.

The SecurAcath has the same intended use as the predicates. The SecurAcath has the same technological characteristics and operating principles as the predicate SecurAcath.

The differences in indication for use of the SecurAcath and the predicates do not raise new questions of safety and efficacy.

The SecurAcath is determined to be substantially equivalent to the Revolution catheter securement device and the presently marketed Interrad Medical SecurAcath (K180769)

8.9 CONCLUSION

The results of these activities demonstrate that the SecurAcath is as safe, as effective, and performs as well as the predicate devices.