June 26, 2018

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

Re: K180769
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: May 21, 2018
Received: May 29, 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. 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 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,

Geeta K. Pamidimukkala -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)*
K180769

Device Name
SecurAcath

Indications for Use *(Describe)*
The SecurAcath device is indicated for short or long term securement of percutaneous indwelling catheters for intravenous use to the access site by means of a subcutaneous anchor.

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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K180769 510(K) SUMMARY

Manufacturer's Name:	Interrad, Inc 181 Cheshire Lane, Suite 100 Plymouth, MN 55441
Corresponding Official:	Denise Lenz Regulatory Consultant, Libra Medical, Inc. 8401 73rd Ave North, Suite 63 Brooklyn Park, MN 55428
Telephone Number:	612-965-3445
Email:	dlenz@libramed.com
Preparation Date:	June 25, 2018
Device Trade Name:	SecurAcath
Device Common or Usual Name:	Implanted subcutaneous securement catheter
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter.
Regulation Number:	21 CFR 880.5970
Product Code:	OKC, KMK
Device Class:	Class II
Classification Panel:	General Hospital
Primary Predicate Device:	K120935; SecurAcath

Purpose of 510(k)
The purpose of this 510(k) is to add the 10F and 12F sized SecurAcath devices to the SecurAcath family to secure 10F and 12F catheters and to update the product specification testing requirements for device fatigue and reliability testing.

Indications for Use
The SecurAcath device is indicated for short or long term securement of percutaneous indwelling catheters for intravenous use to the access site by means of a subcutaneous anchor.

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.

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

Technological Characteristics Comparison

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 changes between the subject device and predicate device is the addition of the 10F and 12F sized SecurAcath devices to the SecurAcath family to secure 10F and 12F catheters. Design changes for the 10F and 12F includes the removal of alignment fingers and the shaft lock shape change to oval.

Characteristic	**Predicate Device: SecurAcath (K120935)**	**Subject Device: SecurAcath (K180769)**	**Comparison**
Indications for Use	The SecurAcath Device is indicated for short or long term securement of percutaneous indwelling catheters for intravenous use to the access site by means of a subcutaneous anchor.	The SecurAcath Device is indicated for short or long term securement of percutaneous indwelling catheters for intravenous use to the access site by means of a subcutaneous anchor.	Same
Regulation Number	21 CFR 880.5970	21 CFR 880.5970	Same
Product Code	OKC, KMK	OKC, KMK	Same
Device Configuration	Single use, sterile device	Single use, sterile device	Same
Catheter compatibility	3F, 4F, 5F, 6F, 7F, 8F	3F, 4F, 5F, 6F, 7F, 8F, 10F, 12F	Different
Biocompatibility	Materials testing in accordance with ISO 10993-1	Identical materials used in new device configurations	Same
Sterility	EtO and SAL of 10-6 In accordance with ISO 11135	EtO and SAL of 10-6 In accordance with ISO 11135	Same

Substantial Equivalence Discussion
The indications for use and intended use of the predicate 510(k) K120935, are equivalent to the subject 510(k) device.

The differences between the subject device and predicate device are the following:

- The additional sizes of 10F and 12F compatibility to the device
- Update the product specification testing requirements to the device fatigue and reliability testing.

The additional sizes (10F, 12F) for SecurAcath have the same principles of operation, same technological characteristics, incorporate the same basic design, incorporate the same materials, have the same shelf life, and are packaged and sterilized using the same materials and processes as the previously cleared predicate device. The changes have been verified/validated through performance testing and risk management activities.

Based on the aforementioned modifications to the subject device, the subject device does not raise different types of safety and effectiveness questions when compared to the predicate device.

Performance Testing Summary
Based on a risk analysis of the changes, the following testing was conducted to demonstrate substantial equivalence to the predicate device:

Performance testing, includes dimensional verification, functional tests and securement reliability. Testing was performed 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
- Joint Tensile Strength
- Base & Cover Interaction
- Hinge performance
- Catheter Securement Performance
- Catheter Interaction

A risk analysis was completed in accordance with ISO 14971:2012, Medical Devices – Applications of Risk Management to Medical Devices.

In all instances, the subject device functioned as intended and demonstrated equivalent performance to the predicate device.

CONCLUSION

The modifications to the device do not raise different questions of safety and effectiveness and are supported by risk management activities. The SecurAcath is substantially equivalent to the Interrad Medical SecurAcath device, cleared under K120935.