November 24, 2020

Global Medikit Limited
% Atonu Dutta, CEO
Meditech Consulting
102, Platinum Avenue, Vikram Society, Gotri Road
Vadodara, Gujarat
India 390021

Re: K193158
Trade/Device Name: ACENT™ Central Venous Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: October 17, 2020
Received: October 30, 2020

Dear Atonu Dutta:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193158

Device Name
ACENT™ Central Venous Catheter

Indications for Use *(Describe)*
ACENT™ Central Venous Catheter is an intravascular catheter, designed for infusion of fluid to the central venous system and/or for pressure measurements.
- for short-term (less than 30 days) infusion therapy or parenteral nutrition
- for continuous or intermittent monitoring of the central venous pressure,
- for blood sampling.

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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510(K) Summary

K193158

I. Submitter

M/s. Global Medikit Limited

Khasra No. 323 (MI) Camp Road,
Selaqui Deharadun,
Uttrakhand, India

Tel. No: +91 11 27667889,

E-mail : regulatory@globalmedikit.in

Web site: www.globalmedikit.in

Contact Person: Mr. Mahendra Singh

Date of Prepare: 24th November 2020

Application Correspondent:

C/o: Atonu Dutta, CEO

Meditech Consulting

102 Platinum Avenue,
Vikram Society, Gotri Road,
Vadodara, Gujarat
INDIA 390021

Tel: (91) 990-5805571

E-mail: medtect.regulatory@gmail.com

II. Device

Trade Name	:	ACENT™ Central Venous Catheter
Common Name	:	Catheter, Intravascular, Therapeutic, Short-term (less than 30 days)
Device Class	:	II
Review Panel	:	General Hospital
Product Code	:	FOZ
Regulation Number	:	21 CFR 880.5200
Regulation Name	:	Intravascular Catheter

III. Predicate Device

Trade Name	:	Able Central Venous Catheter
Manufacture	:	Foshan Nanhai Bai He Medical Technology Co., Ltd
510(K) No.	:	K070451

IV. Device Description

ACENT™ catheters are polyurethane, radiopaque single, double, or triple lumen catheters. The catheter is available in sizes that vary from 4 French through 8 French and lengths 8 cm through 20 cm. Each lumen extends from the vicinity of the distal tip to the main (bifurcation or junction) hub, where it branches via the connector into dedicated extension tubes for infusion of fluids. Each of the extension line has a slide clamp and are labeled to provide identification of the lumen size and location. The catheter body has depth markings, measured in cm from the catheter tips. The extension line marked “distal” is used for device placement with a compatible

guide wire.

The distal tip is soft to minimize patient trauma during insertion. The device is radiopaque to allow verification of location in the patient. Central venous catheters are inserted into a large vein and threaded into the central venous system.

V. Indications for Use

ACENT™ Central Venous Catheter is an intravascular catheter, designed for infusion of fluid to the central venous system and/or for pressure measurements.

- for short-term (less than 30 days) infusion therapy or parenteral nutrition
- for continuous or intermittent monitoring of the central venous pressure,
- for blood sampling.

VI. Substantial Equivalence

The ACENT™ Central Venous Catheter is substantially equivalent to marketed predicate devices with respect to intended use and technological characteristics. The ACENT™ Central Venous Catheter operates on the same principle as predicate device. Comparison Chart of ACENT™ Central Venous Catheter System and Predicate devices is provided below:

Characteristics	Subject Device	Predicate Device	Change
Device Name	ACENT™ Central Venous Catheter	Able Central Venous Catheter	-
510 (K)	K193158	K070451	-
Manufacturer	Global Medikit Ltd.	Foshan Nanhai Bai He Medical Technology Co., Ltd	-
Common Name	Central Venous Catheter	Central Venous Catheter	No Change
Regulation Name	Intravascular Catheter	Intravascular Catheter	No Change
Class	II	II	No Change
Product Code	FOZ	FOZ	No Change
Regulation Number	21 CFR 880.5200	21 CFR 880.5200	No Change
Use duration	Short Term (Less than 30 days)	Short Term (Less than 30 days	No Change
Single Patient Use	Yes	Yes	No Change
Patient Contact	External communicating device circulating blood contact prolonged use (Short term)	External communicating device circulating blood contact prolonged use (Short term)	No Change

Indications for Use	ACENT™ Central Venous Catheter is an intravascular catheter, designed for infusion of fluid to the central venous system and/or for pressure measurements. • for short-term (less than 30 days) infusion therapy or parenteral nutrition • for continuous or intermittent monitoring of the central venous pressure, • for blood sampling.	The Central Venous Catheters including: 14G, 16G, 18G, and 20G in single-lumen catheters; 4F, 5F, 7F, and 8F in double-lumen catheters; are intended for vascular access infusion and withdrawal of blood, blood products, and fluids, plasma pheresis, hyperalimentation, central venous blood sampling and continuous and intermittent drug infusion.	Indications are same. In subject device indication is for general infusion therapy and parenteral nutrition whereas the predicate includes plasma pheresis, and infusion of blood and blood products. The intended use of the subject device is within the scope of the intended use of the predicate.
Catheter Placement method	Percutaneous via Seldinger technique	Percutaneous via Seldinger technique	No Change
Number of Catheter Lumens	1 to 3	1 to 3	No Change
Catheter size			
Single Lumen	4fr, 5fr, 6fr, 7fr (14G,16G,18G)	3fr,4fr,5fr,6fr,7fr (14G,16G,18G,20G)	Sizes are similar except that the Predicate has an additional 3fr (20G) size. Sizes of subject device are within the range of the predicate. The difference will not affect safety and effectiveness of the subject device performance testing is conducted on worst case sizes.

Double Lumen	5fr, 5.5fr, 7fr, 7.5fr	4fr,5fr,7fr,8fr	The subject device has additional sizes (5Fr and 7.5 Fr) that are within the range of the predicate device sizes (4fr and 8fr). The additional sizes will not affect safety and effectiveness of the subject device because performance testing is conducted on worst case sizes.
Triple Lumen	5fr, 5.5fr, 7fr, 7.5fr, 8fr	5.5fr,7fr	The subject device has additional sizes, 5fr,7.5fr, & 8fr. The additional sizes will not affect safety and effectiveness of the subject device because performance testing is conducted on worst case sizes.
Catheter Length			
Single Lumen	15,16 & 20 cm	15,16 & 20 cm	No Change
Double Lumen	15,16 & 20 cm	15,16 & 20 cm	No Change
Triple Lumen	8,12,13, 15,16 & 20cm	8,12,13, 15,16 & 20cm	No Change
Catheter Tip Target anatomy	SVC-RA junction	SVC-RA junction	No Change
Catheter Tip Location Confirmation Method	X-Ray	X-Ray	No Change
Catheter Distal End Configuration	Straight and tapered	Straight and tapered	No Change
Catheter Ink Markings	yes	yes	No Change
Catheter Shaft Material	Polyurethane	Polyurethane	No Change
Catheter Tip & Shaft Material	Polyurethane	Polyurethane	No Change

Lumen Shape	Round, Crescent	Round, Crescent	No Change
Packaging	Plastic Tray with Tyvek Lid stock	Plastic Tray with Tyvek Lid stock	No Change
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	No Change
Sterilization	Ethylene Oxide	Ethylene Oxide	No Change

VII. Performance Data

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

Bench Performance

The performance testing of ACENT™ Central Venous Catheter is carried out on sterilized production lot and per the following standard:

- ISO 10555 -1, "*Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements"*
- ISO 10555-3, "*Intravascular catheters — Sterile and single-use catheters — Part 3: Central venous catheters"*
- ISO 594-1, "*Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements"*
- ISO 594-2, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings*"
- ISO 14971, *"Medical devices - Applications of risk management to medical devices"*
- Particulate testing per USP <788>

Biocompatibility

The biocompatibility evaluation for ACENT™ Central Venous Catheter was conducted in accordance with the guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and ISO 10993-1, "Biological evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process" as recognized by FDA.
As per ISO 10993-1, ACENT™ Central Venous catheter is an external communicating device with prolonged circulating blood contact. Accordingly, the following biological evaluation tests were conducted:

- Cytotoxicity
- Sensitization
- Irritation / Intracutaneous reactivity
- Acute Systemic Toxicity
- Sub Chronic Toxicity Study
- Genotoxicity
- Implantation study
- Hemocompatibility
- Pyrogenicity (Material and Bacterial)

Sterilization

The sterilization process has been validated per AAMI/ANSI/ISO 11135, "*, Sterilization of Health-Care Products - Ethylene Oxide - Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices"* and demonstrated a sterility assurance level of 10^{-6}. Ethylene oxide residuals were tested and met ISO 10993-7, "*Biological*

Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals" requirements.

Packaging & Shelf life

Following packaging and shelf life study was conducted to ensure package integrity throughout the shelf life. The shelf life is established for 2 years.

- Packaging validation as per ISO 11607-1, "*Packaging for terminally Sterilized Medical Devices – Part 1: Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems And Packaging Systems"*
- Shelf life validation as per ASTM 1980, "*Standard guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*" & ISO 11607-1, "*Packaging for terminally Sterilized Medical Devices – Part 1: Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems And Packaging Systems"*

VIII. Conclusion

ACENT™ Central Venous Catheter is substantially equivalent to the predicate device and presents no new questions of safety or effectiveness when compared in design, technological characteristics, performance testing, and intended use to the predicate device.