May 21, 2020

Hakki Medical Technologies, Inc.
Shereen Hakky
Director of Operations
10333 Seminole Boulevard, Suite #8
Largo, FL 33778

Re: K191512
Trade/Device Name: LotusCatheter (Lotus No Balloon Catheter)
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM, FEW
Dated: June 4, 2019
Received: June 7, 2019

Dear Shereen Hakky:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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,

Purva U. Pandya -S

Purva Pandya
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
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)*

K191512

Device Name

LotusCatheter (Lotus No Balloon Catheter)

Indications for Use *(Describe)*

The LotusCatheter (Lotus No Balloon Catheter) is used for continuous drainage of fluid, including continuous bladder irrigation and intermittent catheterization. Drainage is generally accomplished by inserting the catheter through the urethra, suprapubically into the bladder or through a nephrostomy tract. The LotusCatheter (Lotus No Balloon Catheter) is to be used in patients 5 years of age or older.

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.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	June 4, 2019
Submitter:	Hakki Medical Technologies, Inc. Address: 10333 Seminole Boulevard, Suite #8, Largo, Florida 33778
Contact Person:	Shereen Hakky Director of Operations Hakki Medical Technologies, Inc. Telephone: +1-727-415-7448 Email: Shereen@LotusCatheter.com
Device Name:	LotusCatheter (Lotus No Balloon Catheter)
Regulation Number:	876.5130
Regulation Name:	Urological Catheter and Accessories
Product Code:	GBM, FEW
Device Class:	Class II
Review Panel:	Gastroenterology/Urology
Device Description:	The Lotus No Balloon Catheter is a sterile, single patient use drainage catheter made of silicone elastomer. The catheter is used to pass fluids to and from the urinary tract, suprapubically or through the nephrostomy tract. The catheter is supplied in French sizes ranging from 8Fr to 26Fr.
Intended Use:	The Lotus No Balloon Catheter is used for continuous drainage of fluid, including continuous bladder irrigation and intermittent catheterization. Drainage is generally accomplished by inserting the catheter through the urethra, suprapubically into the bladder or through a nephrostomy tract. The Lotus No Balloon Catheter is to be used in patients 5 years of age or older.
Predicate Device(s):	K101900- Latex Hakki Urinary Catheter K070879- Latex Bard Malecot and Pezzer Drains
Substantial Equivalence:	The Lotus No Balloon Catheter described in this 510(k) is the silicone version of its predicate device, the latex Hakki Urinary Catheter (K101900). The Lotus No Balloon Catheter has

similar technological and performance characteristics as the Latex Bard Malecot and Pezzer Drains Device (K070879). The similarities and differences between the proposed and predicate devices have been identified and explained in the comparison matrix which has been included in Section 12 of this submission. Our testing shows these differences have no substantial affect on safety or effectiveness.

Test Data:

The Lotus No Balloon Catheter lacks the balloon retention mechanism present in Foley catheters, therefore some testing was not applicable or was modified to meet the standard set forth in ASTM F623-99:2013; testing of the Lotus No Balloon Catheter was conducted in accordance with modified performance requirements of its predicate device, the Hakki Urinary Catheter (K101900):

- Components Testing
- Flow Rate
- Dimensions
- Expanded Wings Integrity
- Expanded Wings Response to Pullout
- Strength of the Catheter

The Lotus No Balloon Catheter passed biocompatibility testing per ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2010, ISO 10993-11:2017, ISO 10993-6:2016. Testing data and results are included in this submission.