March 20, 2018

EMcision Ltd.
% Louis-Paul Marin
President
LOK North America Inc.
2025 Michelin
LAVAL, H71 5b7
CANADA

Re: K180165
Trade/Device Name: Habib EndoHPB
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS
Dated: January 17, 2018
Received: January 22, 2018

Dear Louis-Paul Marin:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K180165

Device Name
Habib EndoHPB

Indications for Use *(Describe)*
The Habib EndoHPB is a radiofrequency (RF) catheter which provides bipolar energy to perform partial or complete ablation of tissue in the pancreatic and biliary tracts.

The Habib EndoHPB is also intended for use to ablate malignant or benign tissue, notably to perform endoscopic biliary drainage or decompression, prior to stent placement or afterwards, to clear occluded stent.

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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EMcision

510(k) Summary

1. **Type of submission** — Traditional

2. **Preparation Date** — January 17, 2018

3. **Submitter Address**

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4. **Contact Person**

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5. **Identification of the Device**

Proprietary Name/Trade Name	Habib EndoHPB
Regulation Description	Endoscopic electrosurgical unit and accessories
Device Classification	II
Regulation Number	876.4300
Panel	Gastroenterology/Urology
Product Code	KNS

6. **Identification of the Predicate**

Predicate Device Name	Habib EndoHPB
510(k) Number	K083292

7. **Purpose of this Submission**

The main purpose of this submission is to gain clearance to expand the indication for use of the previously cleared Habib EndoHPB (K083292) by including a treatment indication and update the original 510(k) submission to current configurations in terms of shelf life duration and insignificant changes to the labeling.

8. **Intended use of the Subject Device**

The Habib EndoHPB is a radiofrequency (RF) catheter which provides bipolar energy to perform partial or complete ablation of tissue in the pancreatic and biliary tracts.

The Habib EndoHPB is also intended for use to ablate malignant or benign tissue, notably to perform endoscopic biliary drainage or decompression, prior to stent placement or afterwards, to clear occluded stent.

9. Device Description

The Habib EndoHPB is an 8F RF bipolar catheter that consists of a catheter with 2 ring electrodes, introduced via an endoscope's biopsy channel. It has an attached cable which connects the device to an RF Generator. RF is applied to the two electrodes at the top of the catheter so that heat is applied to tissue surrounding the catheter.

10. Performance Data

Compared to the predicate device, there has been no change or modification in design, material, energy source or manufacturing process in the subject device. The only modifications that have required performance testing are the following:

- New claimed shelf-life; and
- Compatibility with new generators.

The results obtained support the claimed 3-year shelf-life and the compatibility with new generators.

11. Clinical Data

The subject device indications for use is significantly different when compared to the predicate device. Therefore, multiple clinical studies are being submitted to demonstrate that the Habib EndoHPB is as safe and effective as the predicate. All the clinical studies provided within this submission have been performed using the subject device and clearly support the new intended use.

12. Electromagnetic and Electrical Testing

Electromagnetic compatibility and electrical safety testing have been performed on the Habib EndoHPB to validate that it meets the requirements of the latest Recognized Consensus Standards:

- IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
- IEC 60601-2-2 Medical Electrical Equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
- IEC 60601-2-18 Medical Electrical Equipment – Part 2-18: Particular Requirements for the Basic Safety and Essential Performance of Endoscopic Equipment

13. **Substantial Equivalence Determination**

The overall technological comparisons between the subject device and the predicate are summarized in the following table:

Item	Predicate Device Habib EndoHPB (K083292)	Subject Device Habib EndoHPB
Substantial Equivalence		
Classification	II	II
Code of Federal Regulation	876.4300	876.4300
Prescription Medical Devices	Yes	Yes
Indications for Use	The Habib EndoHPB is intended to be used in the coagulation of tissue during Endoscopic surgical procedures in the Gastro-intestinal Tract.	The Habib EndoHPB is a radiofrequency (RF) catheter which provides bipolar energy to perform partial or complete ablation of tissue in the pancreatic and biliary tracts. The Habib EndoHPB is also intended for use to ablate malignant or benign tissue, notably to perform endoscopic biliary drainage or decompression, prior to stent placement or afterwards, to clear occluded stent.
Anatomical sites	Gastro-intestinal Tract	Pancreatic and Biliary Tracts
Operating Mode	Bipolar RF energy	Bipolar RF energy
Active Electrode Material	Stainless Steel	Stainless Steel
Catheter Size	7.5F	8F
Number of Active Electrodes	2	2
Electrode Shape	Central electrode assembly and outer ring electrode	Central electrode assembly and outer ring electrode
Delivery Mode	Endoscopic	Endoscopic
Single Use	Yes	Yes
Sterilization	ETO	ETO
Packaging	Coil inside a Tyvek pouch mounted in a carton	Coil inside a Tyvek pouch mounted in a carton
Shelf-Life	6 months	3 years
Compatible Generators	RITA Medical Systems 1500 RITA Medical Systems 1500X Radionics Cosman Coagulator CC-1	RITA Medical Systems 1500 RITA Medical Systems 1500X Olympus ESG-100 Genii GI 4000 ERBE VIO 200 ERBE VIO 300

		ERBATOM ICC 200, 300, 350

The evidence collected in the table above clearly demonstrate that, except for insignificant differences, the subject device, the Habib EndoHPB, is **identical** to the previously cleared Habib EndoHPB (K083292) in terms of fundamental technology, design attributes, materials, features, functions, and performance.

The differences between the subject and the predicate device are as follows:

- Expanded indications for use;
- Extended shelf-life; and
- Compatibility with more generators.

Performance data provided within this submission support the substantial equivalence of the subject device to the predicate. Additionally, clinical and performance data provided demonstrated the Habib EndoHPB to be safe and effective for the expanded indication for use, extended shelf-life, and compatibility with additional generators.

14. Conclusion

The information provided by EMcision in this submission demonstrates that the subject device Habib EndoHPB is substantially equivalent to the currently cleared predicate device (K083292) and raises no new questions of safety and effectiveness.