DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 7, 2016

EMcision Ltd.
% Mr. Me Louis-Paul Marin
LOK North America, Inc.
2025 Michelin
Laval, Quebec H7L 5B7
Canada

Re: K161305
Trade/Device Name: Habib EUS RFA 6700
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, JOS
Dated: May 3, 2016
Received: May 10, 2016

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161305

Device Name
Habib EUS RFA

Indications for Use *(Describe)*
The Habib EUS RFA 6700 is indicated for coagulation and ablation of soft tissue when used in conjunction with compatible radio frequency generator.

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

EMcision International Inc.

510(k) Summary

1. **Type of submission** — Traditional

2. **Preparation Date** — June 27, 2016

3. **Submitter Address**

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Contact: François Poulin

4. **Contact Person**

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5. **Identification of the Device**

Proprietary Name/Trade Name	Habib EUS RFA 6700
Common Name	Monopolar electrosurgical device
Classification Name	Electrosurgical cutting and coagulation device and accessories
Device Classification	II
Regulation Number	878.4400
Panel	79 – General and Plastic Surgery
Product Code	JOS, GEI

6. **Identification of the Predicate**

Predicate Device Name	HABIB EUS RFA 6700
510(k) Number	K150029

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

The HABIB EUS RFA 6700 is indicated for coagulation and ablation of soft tissue when used in conjunction with compatible radio frequency generator.

8. **Device Description**

The Habib EUS RFA 6700 is a catheter that is delivered during an EUS procedure, through 19 Gauge (G) endoscopic needles. The subject device is monopolar configuration and thus, must be used in conjunction with patient grounding pad. RF energy is produced by connecting the catheter to a compatible RF generator via accessory cable. When attached to a generator, RF current is emitted from the exposed portion of the electrode and this current translates into ion agitation within the surrounding tissue, which is converted by friction into heat and induces cellular death by means of coagulation necrosis.

9. **Performance Data**

Performance bench testing, biocompatibility testing and electrical testing were performed on the subject device, which demonstrates that it met the required specifications for the completed design verification, biocompatibility tests, and electrical tests.

The following performance bench tests were performed:

- Trackability and Pushability Test;
- Consistency of Heating Zone and Temperature Test;
- Abrasion Test;
- Mechanical Tests on the Electrical Assembly including Pull Test; Three Points Bending; Test; Compression Test; Fatigue Resistance Test; and Peel Resistance Test;
- Transport Simulation and Package Integrity;
- Accelerated Aging;
- Seal Integrity (visual inspection);
- Bubble Test (package integrity);
- Peel Test (seal strength);
- Ambient Preconditioning;
- Controlled Conditioning;
- Distribution Simulation;
- Design and Usability Validation;
- Functional Validation for Soft Tissue Indication;
- Label Inspection;
- Usability of Pouch;
- Functional testing of catheter insertion in the endoscope needle;
- Deflection Test;
- Mechanical Tests on the Positioning Guide; and
- IPX2 Test.

The following biocompatibility tests were performed:

- ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7:2008 Biological Evaluation of Medical Devices – Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization

10. Electromagnetic and Electrical Testing

Testing was performed per the requirements of the following electromagnetic compatibility and electrical standards:

- IEC 60601-1:2006: Medical electrical equipment – part 1: General requirements for basic safety and essential performance;
- IEC 60601-2-2:2009 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; and
- IEC 60601-2-18:2009 Endoscopic equipment

11. Substantial Equivalence Determination

The subject device, the Habib EUS RFA 6700, is substantially equivalent to legally marketed predicate device (K150029) with respect ton indications for use and technology characteristics. The Table below present side by side comparisons for each major component for each device:

Item	Predicate Device Habib EUS RFA 6700 (K150029)	Subject Device Habib EUS RFA 6700
Similarities		
Classification	II	II
Code of Federal Regulation	878.4400	878.4400
Prescription Medical Devices	Yes	Yes
Indications for Use	The Habib EUS RFA 6700 is indicated for coagulation and ablation of soft tissue when used in conjunction with compatible radio frequency generator.	The Habib EUS RFA 6700 is indicated for coagulation and ablation of soft tissue when used in conjunction with compatible radio frequency generator.
Active Accessory Configuration	Monopolar	Monopolar
Material of electrode tip	Stainless Steel	Stainless Steel
Safety Standards	IEC 60601-1 IEC 60601-2-2 IEC 60601-2-18 ISO 10993-1 ISO 10993-4 ISO 10993-5 ISO 10993-7 ISO 10993-10	IEC 60601-1 IEC 60601-2-2 IEC 60601-2-18 ISO 10993-1 ISO 10993-5 ISO 10993-7 ISO 10993-10 ISO 14971 ASTM D4332 ASTM D642 ASTM D999 ASTM D5276 ASTM F1886 ASTM 2096 ASTM F88 ASTM 1980 ISO 11607-1 ISO 11135

		ISO 11138-1 ISO 11138-2
Performance Tests	- Compatibility with endoscope needle - Trackability and Pushability Test - Consistency of Heating Zone Test - Abrasion Test - Fatigue Bending Resistance Test - Pull Test - Shipping and Transportation Test - Burst Test (Package evaluation) - Package Seal Dye Penetration Test - Functional Validation for Soft Tissue Indication	- Trackability and Pushability Test - Consistency of Heating Zone and Temperature Test - Abrasion Test - Mechanical Tests on the Electrical Assembly including Pull Test; Three Points Bending Test; Compression Test; Fatigue Resistance Test; and Peel Resistance Test - Transport Simulation and Package Integrity - Accelerated Aging - Seal Integrity (visual inspection) - Bubble Test (package integrity) - Peel Test (seal strength) - Ambient Preconditioning - Controlled Conditioning - Distribution Simulation - Design and Usability Validation - Functional Validation for Soft Tissue Indication - Label Inspection - Usability of Pouch - Functional testing of catheter insertion in the endoscope needle - Deflection Test - Mechanical Tests on the Positioning Guide - IPX2 Test
Sterilization	Ethylene Oxide	Ethylene Oxide
Dimension	Shaft Ø 0.33mm	Shaft Ø 0.33mm
Delivery Mode	Endoscopic needle, laparoscopes, ports, trocars	Endoscopic needle, laparoscopes, ports, trocars
Rated Frequency	Up to 460 kHz	480 kHz
Length of the adaptor cable (cm)	200	200
Type of generator plug	8mm Monopolar Jack (PN 5470) and LEMO 9 PIN PAG.MO.9NL.AC65NZ (PN 5250)	8mm Monopolar Jack (PN 5470) and LEMO 9 PIN PAG.MO.9NL.AC65NZ (PN 5250)
Differences		
Shaft insulation	Polyimide tube on PTFE coating,	Polyimide coating over 0.013"

	over 0.013" OD stainless steel core	OD stainless steel core
Shaft-cable electrical junction	SN-AG Solder	Crimping
Coating of wire connections	Plastic	Santoprene overmould
Adaptor	None	Positioning guide

As per the table set forth above, it is clear that the subject device is substantially equivalent to the predicate device and hence, this device is at least as safe and effective as the predicate device.

The predicate device, the Habib EUS RFA 6700, was initially cleared in K150029. The subject device has the same intended use, function and fundamental technology as the predicate device. The differences between the subject device are the following and all pertinent test results supported that they do not raise new issues of safety and effectiveness:

1) Shaft insulation; change from a PTFE coated with polyimide sleeve to a wire with only polyimide coating. The size and type of wire remains the same;
2) Shaft-cable electrical junction; replace soldering of the wire to connecting wire by a crimping operation;
3) Electrical junction insulation; replace plastic cover of wire connections by a Santoprene overmould; and
4) Positioning guide; addition of a mechanical positioning guide to replace between the introducer and the probe.

11. **Conclusion**

The Habib EUS RFA 6700 is substantially equivalent to the predicate Habib EUS RFA 6700 (K150029). The minor differences between the Habib EUS RFA 6700 and the predicate do not raise any new questions of safety or effectiveness. All product performance testing and the electrical testing performance clearly demonstrate that the Habib EUS RFA 6700 is safe and effective.