EMcision LTD.
% Mr. Louis-Paul Marin
MMA Certification Incorporated
2025 Michelin
Laval, Quebec H7L 5B7
Canada

Re: K150029
  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 21, 2015
  Received: May 27, 2015

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" (21CFR 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 -S

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
510(k) Number (if known)
K150029

Device Name
Habib EUS RFA 6700

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
510(k) Summary

1. **Type of submission:** Traditional

2. **Preparation Date**
   June 22, 2015

3. **Submitter**
   **EMcision Ltd.**
   **Address**
   Department of Surgery
   Hammersmith Hospital
   DuCane Road
   London W12 0HS
   United Kingdom
   Phone 1-514-994-9649
   Contact François Poulin

4. **Contact Person:**
   **Louis-Paul Marin,** ing., LL.B., LL.M.
   President, MMA Certification Inc.
   Phone: 1-450-781-1578 ext 225
   Fax: 1-450-681-9663
   Email: lpmarin@groupemma.ca

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:** GEI, JOS

6. **Identification of the Predicate**
   **Predicate Device Name:** ACE Monopolar Attachment
   **510(k) Number:** K123061

   **Predicate Device Name:** LeVeen™ Standard Needle Electrode System
   **510(k) Number:** K140495
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 or 22 Gauge (G) endoscopic needles. The Habib EUS RFA 6700 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 an 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 proposed Habib EUS RFA 6700, 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:

- Compatibility with endoscope needle
- Trackability and pushability test
- Consistency of heating zone
- Abrasive test
- Fatigue bending resistance
- Pull test
- Shipping and transportation test
- Package evaluation using the burst test
- Visual inspection of medical packaging to determine integrity
- Package seal dye penetration test
- Functional validation for soft tissue indication

The following biocompatibility tests were performed:

- Elution Cytotoxicity and Hemolysis
- Implantation Test
- Intracutaneous toxicity
- Acute systemic injection

10. **Electromagnetic and Electrical Testing**

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

11. Substantial Equivalence Determination

The subject device, the Habib EUS RFA 6700 is substantially equivalent to legally marketed predicate devices, the Ace Monopolar Attachment and the LeVeen™ Standard Needle Electrode System with respect to indications for use and technology characteristics. The Table below presents side by side comparisons for each major component of for each device:

<table>
<thead>
<tr>
<th>Item</th>
<th>Predicate Device</th>
<th>Predicate Device</th>
<th>Subject Device</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ace Monopolar Attachment (K123061)</td>
<td>LeVeen™ Standard Needle Electrode System (K140495)</td>
<td>Habib EUS RFA 6700 (K150029)</td>
</tr>
<tr>
<td>Similarities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Classification</td>
<td>II</td>
<td>II</td>
<td>II</td>
</tr>
<tr>
<td>Code of Federal Regulation</td>
<td>878.440</td>
<td>878.4400</td>
<td>878.4400</td>
</tr>
<tr>
<td>Prescription Medical Devices</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Intended Use</td>
<td>The Ace Monopolar Attachment is intended to be used with the compatible ERBE Monopolar Disposable Electrosurgical Pencil for coagulation and cutting of soft tissue when used in conjunction with compatible ERBE Electrosurgical Generator (ESU) System.</td>
<td>The LeVeen™ Needle Electrode Family (which includes the LeVeen™ Standard Needle Electrode System and the LeVeen™ CoAccess™ Needle Electrode System) is intended to be used in conjunction with the RF3000 Generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver.</td>
<td>The Habib EUS RFA 6700 is indicated for coagulation and ablation of soft tissue when used in conjunction with compatible radio frequency generator.</td>
</tr>
</tbody>
</table>
lesions.

<table>
<thead>
<tr>
<th>Active Accessory Configuration</th>
<th>Monopolar</th>
<th>Monopolar</th>
<th>Monopolar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material of electrode tip</td>
<td>Stainless Steel</td>
<td>n/a</td>
<td>Stainless Steel</td>
</tr>
</tbody>
</table>

**Performance Tests**

- Arcing Test
- Charring Test
- Thermal Spread Test
- Dropping Test
- Pulling Test
- Insulated Cannula Outer Diameter
- Cannula Insulation Adhesion
- Cannula Tensile
- Cannula/Array Housing Handle Compression Strength
- 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

**Differences**

<table>
<thead>
<tr>
<th>Sterilization</th>
<th>Gamma irradiation</th>
<th>Ethylene Oxide</th>
<th>Ethylene Oxide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimension</td>
<td>Shaft φ2.35mm</td>
<td>Shaft φ1.5-2.4mm</td>
<td>Shaft φ0.33mm</td>
</tr>
<tr>
<td>Delivery Mode</td>
<td>Electrosurgical pencil</td>
<td>Cannula (percutaneous)</td>
<td>Endoscopic needle, laparoscopes, ports, trocars</td>
</tr>
<tr>
<td>Rated Frequency</td>
<td>n/a</td>
<td>480 kHz</td>
<td>Up to 460 kHz</td>
</tr>
</tbody>
</table>

13. Conclusion

The Habib EUS RFA 6700 is substantially equivalent to the predicates Ace Monopolar Attachment (K123061) and LeVeen™ Standard Needle Electrode System (K140495). The minor differences between the Habib EUS RFA 6700 and the predicates do not raise any new questions of safety or effectiveness. All product performance testing and electrical testing performance clearly demonstrate that the Habib EUS RFA 6700 is safe and effective.