February 21, 2018

ReNovo, Inc.
% Robert Packard
President
Medical Devices Academy, Inc.
345 Lincoln Hill Rd.
Shrewsbury, Vermont 05738

Re: K172647
Trade/Device Name: Reprocessed ArthroCare ENT Coblator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: September 1, 2017
Received: September 1, 2017

Dear Robert Packard:

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,

Jennifer R. Stevenson -S3

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)*
K172647

Device Name
Reprocessed ArthroCare ENT Coblator

Indications for Use *(Describe)*
The Reprocessed ArthroCare ENT Coblators are indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including:

- Adenoidectomy
- Cysts
- Head, Neck, Oral, and Sinus Surgery
- Mastoidectomy
- Myringotomy with Effective Hemorrhage Control
- Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates
- Nasopharyngeal/Laryngeal indications including Tracheal Procedures,
- Laryngeal Polypectomy, and Laryngeal Lesion Debulking
- Neck Mass
- Papilloma Keloids
- Submucosal Palatal Shrinkage
- Submucosal Tissue Shrinkage
- Tonsillectomy (including palatine tonsils)
- Traditional Uvulopalatoplasty (RAUP)
- Tumors
- Tissue in the Uvula/Soft Palate for the Treatment of Snoring

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.

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."

Reprocessed ArthroCare ENT Coblators Device Models Subject to Clearance

OEM Model #	OEM Marketing Name	Picture	OEM 510(k) Number
EICA5872-01	EVAC 70 XTRA WAND		K142999
EICA8872-01	PROCISE XP Wand		K142999
EICA8870-01	PROCISE EZ COBLATION Wand		K070374

K127647 - 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

ReNovo, Inc.
Mark K. Wells
340 SW Columbia St.
Bend OR, 97702 USA
Tel: +1.541.422.8880
Fax: +1.541.422.8881

II. CONTACT PERSON

Mary Vater, BS
Medical Device Academy
345 Lincoln Hill Rd.
Shrewsbury, VT 05738 USA
Tel: +1.913.274-9899
Email: mary@fdaecopy.com

III. DEVICE

Name of Device:	Reprocessed ArthroCare ENT Coblator
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation:	21 CFR §878.4400
Regulatory Class:	Class II
Product Classification Code:	NUJ

IV. PREDICATE DEVICE

Predicate Manufacturer:	ArthroCare Corporation
Predicate Trade Name:	Evac 70 Xtra Plasma Wand with Integrated Cable, PROcise XP Plasma Wand with Integrated Cable
Predicate 510(k):	K142999
Predicate Manufacturer:	ArthroCare Corporation
Predicate Trade Name:	ArthroCare ENT Plasma Wand
Predicate 510(k):	K070374

No reference devices were used in this submission.

V. DEVICE DESCRIPTION

Reprocessed ENT Coblators are radiofrequency (RF) surgical devices which are powered by an RF generator. The device is designed for the hemostasis of blood vessels, dissection, and removal of tissue during otorhinolaryngology (ENT) surgical procedures.

ENT probes vary in their configuration depending on intended usage in their diameter, length, electrode shape, and saline delivery/suction capabilities. The materials of constructions are generally polycarbonate handles, stainless steel shafts, Polyester or Tygon insulation material, tungsten electrodes, alumina ceramic tips and PVC saline delivery/suction tubing lines

VI. INDICATIONS FOR USE

The Reprocessed ArthroCare ENT Coblators are indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including:

- Adenoidectomy
- Cysts
- Head, Neck, Oral, and Sinus Surgery
- Mastoidectomy
- Myringotomy with Effective Hemorrhage Control
- Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates
- Nasopharyngeal/Laryngeal indications including Tracheal Procedures,
- Laryngeal Polypectomy, and Laryngeal Lesion Debulking
- Neck Mass
- Papilloma Keloids
- Submucosal Palatal Shrinkage
- Submucosal Tissue Shrinkage
- Tonsillectomy (including palatine tonsils)
- Traditional Uvulopalatoplasty (RAUP)
- Tumors
- Tissue in the Uvula/Soft Palate for the Treatment of Snoring

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The subject devices and predicate devices are identical in design, technological characteristic, materials, and indications for use. The devices have different product codes with GEI being the product code for an original, non-reprocessed endoscope accessory, and NUJ being the product code for the reprocessed version of the electrosurgical cutting and coagulation accessory..

The devices and predicate devices (K142999, K070374) are identical in the following ways:

- Regulation name: “Electrosurgical cutting and coagulation device and accessory”
- Regulation number: 21 CFR 878.4400
- Regulatory Class: II

The fundamental technological characteristics of the subject devices are identical to the predicate (OEM) devices. The following characteristics were compared in order to demonstrate substantial equivalence:

- Indications for Use – The predicate and subject devices have the same indications for use, both are indicated for “ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery” for the same surgical procedures.

- Materials – All of the materials are identical to the OEM with exception of the insulation. The OEM insulation was removed from the devices and was replaced with a Fluorinated Ethylene Propylene (FEB) insulation. The FEB insulating and electrical properties are equivalent to those properties of the OEM insulation. In addition, biocompatibility testing was performed on the devices with the new insulation material to ensure all of the materials of the reprocessed device were biocompatible.

- Design – The predicate and subject devices are identical in design.

- Energy Source – The predicate and subject devices are both powered by the same energy source, external RF Generators.

- Performance Testing – The subject devices are reprocessed versions of the predicate (OEM) devices. The OEM devices are performance-tested cleared medical devices; therefore the performance testing consisted of side-by-side testing of the reprocessed devices to an identical new OEM device. This testing included thermal performance, drop testing, and electrical safety and EMC testing.

VIII. PERFORMANCE DATA

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

Performance Testing

- Cleaning
  - Residual Protein and Carbohydrates
  - Visual Inspection
  - Cleaning Performance Qualification
- Functional
  - Thermal Effects Performance Testing
  - Probe Drop Performance Testing
- Sterilization and Packaging
  - EtO Sterilization Testing
  - EtO Residuals Testing
  - Simulated Shipment Testing
- Product Stability
  - Shelf Life Testing 1-year Accelerated Aging

Biocompatibility Testing

The devices are identical to the OEM, except for the OEM insulation which is replaced during reprocessing with Fluorinated Ethylene Propylene (FEP). The following biocompatibility tests were conducted to ensure the safety of the devices:

- Cytotoxicity
- Irritation
- Acute Systemic
- Material Mediated Pyrogenicity
- Sensitization

Reprocessing/Cleaning Residuals Testing

Even though the devices pass biocompatibility testing, additional testing was performed on the reprocessed device to ensure that detergent residuals from the reprocessing were not present on the device.

- Detergent Residuals Testing

Electrical safety and electromagnetic compatibility (EMC)

The following electrical safety and EMC tests have been performed:

- IEC 60601-1-2 EMC Testing
- IEC 60601-2-2 Electrical Safety Testing (high frequency equipment/accessories)

Software Verification and Validation Testing

Software Testing is not applicable, because the device does not contain software.

Mechanical and acoustic Testing

Mechanical and acoustic performance testing was not required to demonstrate safety and effectiveness of the device.

Animal Study

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Clinical Studies

Clinical testing was not required to demonstrate the safety and effectiveness of the Reprocessed ArthroCare ENT Coblator. Instead, substantial equivalence is based upon benchtop performance testing.

IX. CONCLUSIONS

Based on a comparison of technological characteristics, indications for use, and performance data, it can be concluded that the proposed Reprocessed ArthroCare ENT Coblators are substantially equivalent to the predicate device.