March 19, 2018

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

Re: K173740
Trade/Device Name: Reprocessed DePuy Mitek Ablation Wand
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: February 14, 2018
Received: February 15, 2018

Dear Mr. 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)*
K173740

Device Name
Reprocessed DePuy Mitek Ablation Wand

Indications for Use *(Describe)*
The Reprocessed DePuy Mitek Ablation Wands for use with the VAPR Electrosurgical System are intended for resection, ablation, excision of soft tissues, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, hip, ankle, elbow and wrist.

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.

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K173740 Reprocessed DePuy Mitek Ablation Wands – Device Models Subject to Clearance

OEM Model Number	Name	Tip Diameter	OEM 510(k)	Picture
228146	VAPR COOLPULSE 90	3.3mm	K113545 K100638	
228147	VAPR COOLPULSE 90 (w/ HC)	3.3mm	K113545 K100638	
227204	VAPR Premiere 90	3.3mm	K113545 K100638	
227504	VAPR Premiere 50	3.0mm	K113545 K100638	
228504	VAPR Premiere 50 (w/ HC)	3.0mm	K113545 K100638	
225370	VAPR S90	4.0mm	K122425	
228370	VAPR S90 (w/ HC)	4.0mm	K122425	
225361	LPS (2-Piece Electrode)	4.0mm	K113545	
225360	LDS (2-Piece Electrode)	4.0mm	K113545	
227355	VAPR S50	3.0mm	K122425	

K173740 - 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

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III. DEVICE

Name of Device:	Reprocessed DePuy Mitek Ablation Wand
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation:	21 CFR §878.4400
Regulatory Class:	Class II
Product Classification Code:	NUJ

IV. PREDICATE (OEM) DEVICES

Predicate Manufacturer:	DePuy Mitek
Predicate Trade Name:	VAPR Electrodes
Predicate 510(k):	K113545

Predicate Manufacturer:	DePuy Mitek
Predicate Trade Name:	VAPR Electrodes
Predicate 510(k):	K100638

Predicate Manufacturer:	DePuy Mitek
Predicate Trade Name:	VAPR P50 Electrode, VAPR S50 Electrode, VAPR S90 Electrode, VAPR P50 Electrode with handcontrols, VAPR S90 Electrode with Handcontrols
Predicate 510(k):	K122425

No reference devices were used in this submission.

V. DEVICE DESCRIPTION

Reprocessed DePuy Mitek Ablation Wands are radiofrequency surgical devices intended for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures. Ablation wands are powered by a radiofrequency generator or controller. The device variations include various diameters, lengths, or electrode configurations. The materials of construction are generally polycarbonate handles, stainless steel shafts, PET insulation, tungsten

electrodes, alumina ceramic tips and PVC suction lines. The electrode design contributes to the performance differences across different model devices.

VI. INDICATIONS FOR USE

The Reprocessed DePuy Mitek Ablation Wands for use with the VAPR Electrosurgical System are intended for resection, ablation, excision of soft tissues, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, hip, ankle, elbow and wrist.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The fundamental technological characteristics of the subject device are identical to the predicate. The subject devices are reprocessed versions of the predicate devices. Validation was done to ensure that the reprocessing activities did not affect the form or function of the device, and that the reprocessed device performs as well as the original, new device.

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

- Indications for Use – The predicate and subject device have substantially equivalent intended uses. Both are intended for resection, ablation, excision of soft tissues, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, hip, ankle, elbow and wrist.

- Materials – The subject devices are identical reprocessed versions of the predicate OEM devices, therefore the subject devices materials are identical to the predicate.

- Design – The predicate and subject devices are identical in design. No design changes are made during reprocessing.

- Energy Source – The predicate and subject devices are both powered by external RF Generators.

- Performance Testing – The subject devices were tested side by side with predicate devices for thermal effects, probe bending, and probe drop performance. The subject device performed equivalent to the predicate

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 Bending 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
  - Real-Time Shelf Life studies are on-going and are not complete for inclusion in this submission.

Biocompatibility Testing

The following biocompatibility tests were conducted to ensure the safety of the devices:

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

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 DePuy Mitek Ablation Wand. 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 DePuy Mitek Ablation Wand devices are substantially equivalent to the predicate (OEM) devices.