May 22, 2020

Adeor Medical AG
% Cassie Sopko, Regulatory Engineer
JALEX Medical
30311 Clemens Rd, Suite 5D
Westlake, Ohio 44145

Re: K191847
Trade/Device Name: Adeor Medical nxt Non-stick Bipolar Forceps, Adeor Medical nxt Single-Use Non-stick Bipolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 15, 2020
Received: April 20, 2020

Dear Cassie Sopko:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K191847

Device Name
Adeor Medical AG nxt™ Non-stick Bipolar Forceps
Adeor Medical AG nxt™ Single-Use Non-stick Bipolar Forceps

Indications for Use *(Describe)*
The Adeor Medical Non-stick Bipolar Forceps are intended for use by a physician familiar with electrosurgery in bipolar coagulation for general open surgery where coagulation of soft tissue is needed. Adeor bipolar forceps must be operated with the following parameters: Frequency range between 300 kHz and 1,000 kHZ; maximum generator operating voltage 600Vp.

The Adeor Medical Non-stick Bipolar Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

The types of surgery intended include:
- ENT
- Gynecology (except for use in female sterilization)
- Urology
- General surgery
- Neurosurgery
- Laryngeal Surgery
- Orthopedic Surgery
- Thoracic Surgery

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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510(k) Summary

Submitted By: Adeor Medical AG
Biberger Str. 93
82008 Unterhaching
Germany

Date: February 27, 2020

Contact Person: Cassie Sopko, Regulatory Engineer
Contact Telephone: (440) 541-0060
Contact Fax: (440) 933-7839

Device Trade Name: Adeor Medical nxt™ Non-stick Bipolar Forceps
Adeor Medical nxt™ Single-Use Non-stick Bipolar Forceps
Device Classification Name: Electrosurgical, Cutting and Coagulation Accessories
Device Classification: II
Reviewing Panel: General and Plastic Surgery
Product Code: GEI
Predicate Device: K182773 Falhaber Pinzetten OHG Non-Stick Bipolar Forceps (never subject to recall)
Reference Predicates: K101080- Faulhaber Non-Stick Bipolar Forceps
K162469- CODMAN VersaTru Non-Stick Bipolar Forceps
K130669- Olsen Medical Electrosurgical Monopolar and Bipolar Forceps (subject to recall Z-1944-2018 and Z-1945-2018 for packaging risks)

Device Description:
The Adeor Medical AG Bipolar Forceps are electrosurgical instruments used to grasp, manipulate, cut or coagulate tissue. Bipolar forceps have various lengths and tip configurations, as well as irrigation and suction technologies. Both reusable and single-use forceps are available, with flat plug or two pin plug configurations. Bipolar forceps are connected through a suitable bipolar cable with the bipolar output of a high frequency generator and may be used only with bipolar coagulation current. Adeor bipolar forceps must be operated with the following parameters: Frequency range between 300 kHz and 1,000 kHz: maximum generator operating voltage 600V_p.

Intended Use:
The Adeor Medical Non-stick Bipolar Forceps are intended for use by a physician familiar with electrosurgery in bipolar coagulation for general open surgery where coagulation of soft tissue is needed. Adeor bipolar forceps must be operated with the following parameters: Frequency range between 300 kHz and 1,000 kHZ; maximum generator operating voltage 600Vp.

The Adeor Medical Non-stick Bipolar Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

The types of surgery intended include:

- ENT
- Gynecology (except for use in female sterilization)
- Urology
- General Surgery
- Neurosurgery
- Laryngeal Surgery
- Orthopedic Surgery
- Thoracic Surgery

Summary of Technological Characteristics:
The Adeor Medical Bipolar Forceps are identical to the predicate in that they are both intended to grasp, manipulate and coagulate soft tissue. The subject device's component materials, fundamental scientific technology, and mode of action are identical to that of the predicate device. See Table 1 for a more detailed comparison of the subject, predicate and reference devices.

Table 1: Subject-Predicate Comparison

Item	Adeor Medical	Faulhaber Pinzetten	CODMAN VersaTru	OLSEN Medical®	Comparison to Predicate
Classification Name	Electrosurgical, Cutting and Coagulation Accessories	Electrosurgical, Cutting and Coagulation Accessories	Electrosurgical, Cutting and Coagulation Accessories	Electrosurgical, Cutting and Coagulation Accessories	Equivalent
Regulation	878.4400	878.4400	878.4400	878.4400	Equivalent
Common Name	Single-Use and Reusable Bipolar Forceps	Non-stick Bipolar Forceps	Disposable Bipolar Forceps	Single Use Bipolar and Monopolar Forceps Multiple-Use Bipolar and Monopolar Forceps	Equivalent
Product Code	GEI	GEI	GEI	GEI	Equivalent

Intended Use	The Adeor Medical Non-stick Bipolar Forceps are intended for use by a physician familiar with electrosurgery in bipolar coagulation for general open surgery where coagulation of soft tissue is needed. Adeor bipolar forceps must be operated with the following parameters: Frequency range between 300 kHz and 1,000 kHZ; maximum generator operating voltage 600Vp. The Adeor Medical Non-stick Bipolar Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures. The types of surgery intended include: • ENT • Gynecology • Urology • General Surgery • Neurosurgery	Faulhaber Single Use Non-Stick Bipolar Forceps sterile/ non-sterile and Single Use NonStick Irrigating Forceps sterile/ non-sterile are intended for use by a physician familiar with electrosurgery for bipolar coagulation and irrigation of tissue for general surgery. The bipolar forceps are used with the bipolar output for standard electrosurgical generators. The products are intended for single use and are provided sterile as well as non sterile. Products supplied non sterile must be cleaned, disinfected and sterilized prior to their use by the validated cleaning, disinfection and sterilization process. The bipolar forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures. The types of surgery intended are - General surgery - Laryngeal coagulation - Orthopedic coagulation - Thoracic coagulation - Neurosurgical coagulation - Gynecological	Intended for use in electrosurgery for coagulation of tissue.	Active electrosurgical devices where monopolar or bipolar electrosurgical cutting and coagulation is desired during surgery and are intended to grasp, manipulate cur or coagulate selected soft tissue.	Equivalent- Subject device includes specific information such as operational frequency range

Item	Adeor Medical	Faulhaber Pinzetten	CODMAN VersaTru	OLSEN Medical®	Comparison to Predicate
	• Laryngeal Surgery • Orthopedic Surgery • Thoracic Surgery	coagulation (except for use in female sterilization) - Urological coagulation - Ear-, Nose- and Throat coagulation.			
Sterility	Gamma Irradiation/ Steam	Gamma Irradiation/ Steam	Gamma Irradiation	Irradiation	Equivalent
Usage	Single-Use and Reusable	Single use (K182773) and Reusable (K101080)	Single- Use	Single and Reusable	Equivalent
Tip Material	Ag 800 (80% pure silver)	Sterling Silver	Plated aluminum	Stainless Steel	Equivalent
Arm Material	Stainless Steel (ISO 7153)	Stainless Steel	Stainless Steel and Titanium	Stainless Steel	Equivalent
Arm Coating	Polyamide	Nylon	Polyamide	Ceramic-Metallic	Equivalent
Size (overall length)	5-10”	8-12”	7-9”	7-9”	Equivalent
Size (distal tips)	0.2-1.5mm	0.5-1.5mm	0.5-1.5mm	0.5-1.5mm	Equivalent
Packaging	PETG Tray, Tyvek Lid	Foil pouch	PETG Tray, Tyvek Lid	Tyvek/film pouch	Equivalent
Electrical Safety Testing	IEC 60601-2-2	IEC 60601-2-2	IEC 60601-1-2 IEC 60601-2-2	IEC 60601-2-2	Equivalent

Non-Clinical Testing:

Electrical Safety
Electrical Safety Testing was performed on the Adeor Bipolar Forceps per IEC 60601-2-2: 2017 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. Isolation of active accessories, high-frequency leakage currents, high-frequency dielectric strength, and mains frequency dielectric strength testing was performed. Instruments did not show any signs of impairment or loss of mechanical function; therefore, testing was successfully completed.

Non-Clinical

Wear
The device is not manufactured from a novel material and does not contain articulating components. There is no concern for wear or debris.

Function
Drop testing was performed on the bipolar forceps to ensure that dropping the device will not cause damage to the device nor loss of functionality. Forceps were dropped multiple times and inspected for grasping capabilities, frequency output, and visual damage. All test articles met the acceptance criteria.

Mechanical Strength
Due to the high strength of the material and the low forces that the device may be subject to, there is no concern for mechanical strength of the forceps. Testing specific to the strength of the device is not necessary.

System Testing
The Adeor forceps are identical to the predicate in design, materials, manufacturing, manufacturer and function. No further performance testing is required.

Conclusion:
Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.