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

September 9, 2016

Arthrex, Inc.
Mr. William Heard
Regulatory Affairs Project Manager
1370 Creekside Blvd.
Naples, Florida 34108-1945

Re: K161581
Trade/Device Name: Arthrex Synergy RF System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 25, 2016
Received: August 29, 2016

Dear Mr. Heard:

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 Part 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 Parts 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,

Christopher J. Ronk -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

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)*
K161581

Device Name
Arthrex Synergy RF System

Indications for Use *(Describe)*

RF Console
The Arthrex Synergy RF System, when used with an Apollo RF Ablation Device (Probe), is intended for use as a complete system in the resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures. Specifically, the ablation devices, electrosurgical generator and their accessories are used for arthroscopic surgery of the shoulder, wrist, hand, elbow, hip, knee, foot and ankle.

RF Probe
The RF Probe are accessories to the Synergy RF Console and are intended for use as a complete system in the resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels and tissue in arthroscopic and orthopedic procedures. Specifically, the RF probes, Synergy RF Console and their accessories are used for arthroscopic surgery of the shoulder, wrist, hand, elbow, hip, knee, foot and ankle.

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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Food and Drug Administration
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510(k) Summary

Date Summary Prepared	August 25, 2016
Manufacturer/ Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	William Heard Regulatory Affairs Project Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643-5553, ext.71813 Fax: 239/598-5508 Email: William.Heard@arthrex.com
Trade Name	**Arthrex Synergy RF System**
Common Name	Electrosurgical, Cutting & Coagulation device and accessories
Product Code ***Classification Name*** ***CFR*** ***Classification***	**GEI** Electrosurgical cutting and coagulation device and accessories 21 CFR 878.4400: An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current. Class II
Review Panel	General & Plastic Surgery
Predicate Devices	ArthroCare System 12000 (K082666)
Purpose of Submission	This **traditional 510(k)** premarket notification is submitted to obtain clearance for the **Arthrex Synergy RF System**.
Device Description	The Arthrex Synergy RF System consists of the Arthrex Synergy RF Generator/Console, Apollo RF probe/ablator and the Synergy RF Footswitch. The system is designed specifically to work together and is not compatible with any other electrosurgical generator. The aspirating RF probe/ablator provides a bipolar electrosurgical effect to target issue. Located on the top of the

	RF probe/ablator handle, the black button adjusts the default power setting for the specific RF probe/ablator connected to the Synergy RF console; the button with the yellow ablate invokes the Ablate function and the blue coagulation button invokes the Coagulation function. A Synergy RF Footswitch can be connected to the front panel of the console to override the control buttons. The user has the option to override this feature through the console touch screen options.
Intended Use	**RF Console** The Arthrex Synergy RF System, when used with an Apollo RF Ablation Device (Probe), is intended for use as a complete system in the resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures. Specifically, the ablation devices, electrosurgical generator and their accessories are used for arthroscopic surgery of the shoulder, wrist, hand, elbow, hip, knee, foot and ankle. **RF Probe** The RF Probe are accessories to the Synergy RF Console and are intended for use as a complete system in the resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels and tissue in arthroscopic and orthopedic procedures. Specifically, the RF probes, Synergy RF Console and their accessories are used for arthroscopic surgery of the shoulder, wrist, hand, elbow, hip, knee, foot and ankle.
Summary of Performance Testing	The performance testing of the Arthrex Synergy RF System has been shown to be substantially equivalent to the predicate ArthroCare 12000 system by evaluation of coagulation/ablation zone measurements and/or visual similarity of coagulation/ablation of tissue samples, and with respect to the measured temperatures of adjacent tissue, in-vitro.
Substantial Equivalence Summary	**Arthrex Synergy RF System** is substantially equivalent to the predicate device ArthroCare System 12000 based on the same indications, FDA product code, CFR Regulation number, classification and indications for use. Any differences between the **Arthrex Synergy RF System** and the predicate are considered minor and do not raise questions concerning safety and effectiveness. The proposed device is substantially equivalent to the predicate device in regards to its intended use, design, energy source and function.

	The submitted performance testing data demonstrated that the coagulation and ablation of the proposed device is substantially equivalent to the coagulation and ablation of the predicate device.
Conclusion	Based on the indications for use, intended use, biocompatibility, technological characteristics, and the comparison of the performance testing to the predicate device, Arthrex, Inc. has determined that the **Arthrex Synergy RF System** is substantially equivalent to the currently marketed predicate device.