



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 15, 2016

ArthroCare Corporation
Ms. Krystle Danuz
Regulatory Affairs Specialist
7000 West William Cannon Drive
Austin, Texas 78735

Re: K153675

Trade/Device Name: Paragon T2 Wand with Integrated Cable
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 16, 2015
Received: December 21, 2015

Dear Ms. Danuz:

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" (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 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

Indications for Use

510(k) Number (if known)

K153675

Device Name

Paragon T2 Wand with Integrated Cable

Indications for Use (Describe)

Please see attached.

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)



Indications for Use

The ArthroCare ArthroWands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures:

Arthroscopic and Orthopedic Procedures	Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)
<i>Ablation and Debridement</i>	
• ACL/PCL	Knee
• Acromioplasty	Shoulder
• Articular Cartilage	All Joints
• Bursectomy	All Joints
• Chondroplasty	All Joints
• Facia	All Joints
• Ligament	All Joints
• Notchplasty	Knee
• Scar Tissue	All Joints
• Soft Tissue	All Joints
• Subacromial Decompression	Shoulder
• Synovectomy	All Joints
• Tendon	All Joints
<i>Excision and Resection</i>	
• Acetabular Labrum	Hip
• Articular Labrum	All Joints
• Capsule	All Joints
• Capsular Release	Knee
• Cartilage Flaps	Knee
• Cysts	All Joints
• Discoid Meniscus	Knee
• Frozen Shoulder Release	Shoulder
• Glenoidale Labrum	Shoulder
• Lateral Release	Knee
• Ligament	All Joints
• Loose Bodies	All Joints
• Meniscal Cystectomy	Knee
• Meniscectomy	Knee
• Plica Removal	All Joints
• Scar Tissue	All Joints
• Soft Tissue	All Joints
• Synovial Membrane	All Joints
• Tendon	All Joints
• Triangular Fibrocartilage (TFCC)	Wrist
• Villusectomy	Knee
<i>Coagulation</i>	
• ACL/PCL	Knee
• Articular Cartilage	All Joints
• Carpal Ligaments	Wrist

Arthroscopic and Orthopedic Procedures	Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)
• Glenohumeral Capsule	Shoulder
• Ligament	All Joints
• Medial Retinaculum	Knee
• Rotator Cuff	Shoulder
• Tendon	All Joints
• Wrist Tendons	Wrist

510(k) Summary

ArthroCare Corporation

Paragon T2 Wand with Integrated Cable

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name: ArthroCare Corporation

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Contact Person: Ms. Krystle Danuz, B.A., B.S.
Regulatory Affairs Specialist
Phone: 512-385-5769
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Date Prepared: December 16, 2015

Device Name

Proprietary Name: Paragon T2 Wand with Integrated Cable

Common Name: Electrosurgical devices and accessories

Classification Name: Electrosurgical cutting and coagulation device and accessories

Device Class: Class II

Product Code: GEI

CFR Section: 21 CFR 878.4400

Predicate Device

ArthroCare ArthroWands (Paragon T2 Wand with Integrated Cable)

K033584
(November 28, 2003)

Description

The ArthroCare ArthroWands are bipolar, single use, sterile, high frequency electrosurgical devices designed for specific indications in arthroscopic and orthopedic procedures.

The Paragon T2 Wand with Integrated Cable is a part of the family of ArthroCare ArthroWands and is specifically indicated for resection, ablation, and coagulation of soft tissue, and hemostasis of blood vessels in arthroscopic and orthopedic procedures of the knee.

Consistent with the predicate device, the Paragon T2 Wand with Integrated Cable is compatible with the System 2000, Quantum, Quantum 2, or Atlas System Controllers. The controller is designed to deliver radiofrequency energy to the active electrode(s) at the distal end of the wand. The Wand is designed for soft tissue procedures where tissue resection, ablation, coagulation, and hemostasis are desired.

The wand consists of an active electrode, temperature indicator epoxy, a return electrode, a spacer, insulation, a connector block, a bent bead blasted shaft, nylon tubing, and a handle that connects via an integrated cable to the controller. The cable consists of wires that communicate with the active and return electrodes as well as the controller.

The Paragon T2 Wand with Integrated Cable is a Coblation wand designed to effectively ablate articular cartilage with minimal thermal effect on surrounding tissue. This Wand incorporates a Temperature Indicating Marker (TIM) as a visual indicator to the user that the temperature around the tip has reached 43°C-57°C degrees.

Intended Use/Indications For Use

The ArthroCare ArthroWands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures:

Arthroscopic and Orthopedic Procedures	Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)
<i>Ablation and Debridement</i>	
• ACL/PCL	Knee
• Acromioplasty	Shoulder
• Articular Cartilage	All Joints
• Bursectomy	All Joints
• Chondroplasty	All Joints
• Facia	All Joints
• Ligament	All Joints
• Notchplasty	Knee
• Scar Tissue	All Joints
• Soft Tissue	All Joints
• Subacromial Decompression	Shoulder
• Synovectomy	All Joints
• Tendon	All Joints
<i>Excision and Resection</i>	
• Acetabular Labrum	Hip
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• Capsule	All Joints
• Capsular Release	Knee
• Cartilage Flaps	Knee
• Cysts	All Joints
• Discoid Meniscus	Knee
• Frozen Shoulder Release	Shoulder
• Glenoidale Labrum	Shoulder
• Lateral Release	Knee

Arthroscopic and Orthopedic Procedures	Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)
• Ligament	All Joints
• Loose Bodies	All Joints
• Meniscal Cystectomy	Knee
• Meniscectomy	Knee
• Plica Removal	All Joints
• Scar Tissue	All Joints
• Soft Tissue	All Joints
• Synovial Membrane	All Joints
• Tendon	All Joints
• Triangular Fibrocartilage (TFCC)	Wrist
• Villusectomy	Knee
Coagulation	
• ACL/PCL	Knee
• Articular Cartilage	All Joints
• Carpal Ligaments	Wrist
• Glenohumeral Capsule	Shoulder
• Ligament	All Joints
• Medial Retinaculum	Knee
• Rotator Cuff	Shoulder
• Tendon	All Joints
• Wrist Tendons	Wrist

Summary of Technological Characteristics

No changes or modifications have been made to the indications for use, technology, or principle of operation previously cleared in 510(k) K033584. The following table represents a summary of the technological characteristics of the modified device.

	<u>PREDICATE DEVICE:</u> ArthroCare ArthroWands (K033584)	<u>MODIFIED DEVICE:</u> Paragon T2 Wand with Integrated Cable
Electrical Safety/EMC	IEC 60601-2-2 compliant	Same as predicate
Electrode Configurations	Straight, Screen, Loop, Sheet, “Multi-Electrodes in Series”, Tube	Loop
Spacer Configurations	Multi-Lumen, Single Lumen (Tube)	Single Lumen
Rigid Construction	Yes	Same as predicate
Single use disposable	Yes	Same as predicate
Operates in saline environment	Yes	Same as predicate
Bipolar/monopolar	Bipolar	Same as predicate
Activation	Foot Control, Hand Switch or Wand with Integrated Finger Switch	Hand Switch or Foot Control

Coagulation Voltage Setting	Non-adjustable (1 set point) Adjustable (3 set points), 2 Active Set Points	Adjustable (3 set points)
Temperature Indicating Marker	Yes	Yes
Bendable Shaft Feature	No	Yes
Patient Usage	Single Use	Same as predicate
Sterilization	Irradiation to SAL of 10 ⁻⁶	Same as predicate

Clinical Data

No clinical data are included in this submission.

Performance Data

Performance bench testing, including functional testing, ablation life, and biocompatibility testing were performed on the proposed Paragon T2 Wand with Integrated Cable, which demonstrated the modified temperature sensitive dye met the required specifications.

Testing Type	Test Description	Result Supporting Substantial Equivalence
Verification Testing	<ul style="list-style-type: none"> ▪ Visual Inspection ▪ TIM Color Change (Pre-Ablation and Post-1X Life Ablation) ▪ Ablation 1X Life / 1st Insertion Testing ▪ Ablation 2X Life Testing ▪ Ablation 3X Life Testing at Maximum Set Point ▪ Coagulation Testing ▪ Dielectric Withstand / HiPot Testing ▪ Side Load Testing ▪ Ablation Testing ▪ Temperature Testing ▪ Accelerated Aging 	Both the Paragon T2 Wand with Integrated Cable and predicate device have substantially equivalent testing specifications and both performed within acceptance criteria. These results support that the Paragon T2 Wand with Integrated Cable and predicate device are substantially equivalent.
Biocompatibility Testing	<ul style="list-style-type: none"> ▪ Cytotoxicity ▪ Sensitization ▪ Irritation ▪ Toxicity ▪ Chemical Analysis 	The Paragon T2 Wand with Integrated Cable and the predicate device are biocompatible. These results support that the Paragon T2 Wand with Integrated Cable and predicate device are substantially equivalent.

Conclusion

All testing demonstrates that the Paragon T2 Wand with Integrated Cable performs as intended and has acceptable mechanical properties when used in accordance with its labeling.

As the intended use, operating principle, materials and technological characteristics are unchanged from the predicate device, the Paragon T2 Wands with Integrated Cable are substantially equivalent. The modifications do not affect the safety or efficacy of the devices.