K120791

DEC 11 2012

510(k) Summary

ARTHROCARE® CORPORATION
Ambient ®TurboFlash™ 90 IFS

General Information

Submitter Name:	ArthroCare Corporation
Address:	7000 West William Cannon Drive Austin, TX 78735
Contact Person:	Cheryl Frederick Director, Regulatory Affairs
Date Prepared:	October 8, 2012

Device Description

Proprietary:	Ambient ®TurboFlash™ 90 IFS Wand
Common:	Electrosurgical Cutting and Coagulation and Accessories
Classification:	Class II
Product Code:	GEI
CFR Section:	21 CFR 878.4400

Predicate Device

Ambient Super TurboVac® 90 IFS Wand included in:

ArthroCare ArthroWand Devices, K083306

Product Description

The Ambient TurboFlash 90 IFS Wand is a bipolar, sterile, single-use, high frequency electrosurgical device which consists of a distal electrode tip composed of tungsten and titanium, a ceramic spacer-cap, a stainless steel shaft, internal suction tubing, and a molded handle with integrated finger switches. The Ambient TurboFlash 90 IFS is only compatible with the Quantum™ 2 Controller which incorporates a "Use Limiting" feature that prevents the re-use of the device..

Intended Uses/Indications for Use

The Ambient TurboFlash 90 IFS is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures including:

Arthroscopic and Orthopedic Procedures	**Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)**
Ablation and Debridement	
• ACL/PCL	Knee
• Acromioplasty	Shoulder
• Articular Cartilage	All Joints

Arthroscopic and Orthopedic Procedures	Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)
• Bursectomy	All Joints
• Chondroplasty	All Joints
• Fascia	All Joints
• Ligament	All Joints
• Notchplasty	Knee
• Scar Tissue	All Joints
• Soft Tissue	All Joints
• Subacromial Decompression	Shoulder
• Synovectomy	All Joints
• Tendon	All Joints
Excision and Resection	
• 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
• Glenoid 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
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

This Special 510(k) proposes modifications to the specifications for the Ambient Super TurboVac 90 IFS most recently cleared in K083306. The indications for use, fundamental scientific technology, principle of operation, and sterilization methodology remain the same as in previously cleared 510(k). The following table summarizes the technological differences between the subject device, the Ambient TurboFlash 90 IFS, and the predicate device, the Ambient Super TurboVac IFS 90).

Ambient TurboFlash 90 IFS (Subject Device)	Ambient Super TurboVac IFS, K083306 (Predicate Device)	Rationale for Change
One-piece spacer-cap design manufactured from alumina.	Two-piece spacer-cap manufactured from alumina and stainless steel, respectively.	Facilitates the manufacturability of a smaller profile tip which provides the surgeon better access to tight joint spaces
Screen is secured to the spacer-cap with two tungsten raised staples. The screen and staples are energized via a titanium electrode leg which passes through the spacer-cap via an internal pathway ad conducts power from the Quantum 2 Controller to the screen.	Screen is energized and secured to the spacer with four tungsten ball wires which pass through the spacer and cap via an internal pathway and conduct power from the Quantum 2 Controller to the screen.	These design changes are being proposed to provide: ▪ more efficient manufacturability; and ▪ a smaller profile tip to provide surgical access to tight joint spaces.
Resistor in the connector of the wand cable allows for a maximum ablation set point of 10.	Resistor in the connector of the wand cable allows for a maximum ablation set point of 9.	Provides the surgeon more flexibility in delivering therapy.

As a result of these modifications, the corresponding product labeling has also been updated.

Summary of Non-Clinical Performance Testing

In establishing substantial equivalence to the predicate device, ArthroCare compared the intended use, as well as features including materials, physical specifications, performance specifications and sterilization parameters. In addition, the Ambient TurboFlash 90 IFS was successfully evaluated using a variety of bench tests to simulate clinical use including:

- Ablation and coagulation testing;
- Electrical safety testing including Hipot, continuity, and IEC 60601-2-2:2009;
- Tip strength testing;
- Suction rate testing;
- *Ex vivo* performance testing; and
- Ambient temperature measurement testing.

This testing demonstrated that the proposed modifications for the Ambient TurboFlash 90 IFS are substantially equivalent and do not affect the safety or efficacy of the device.

Summary of Safety and Effectiveness

The Ambient TurboFlash 90 IFS is substantially equivalent to the Ambient Super TurboVac 90 IFS cleared via K083306. Both the subject and the predicate devices have the same indications for use and utilize the same fundamental scientific technology. The proposed modifications are not substantial and do not significantly affect the safety or efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Arthrocare Corporation
% Ms. Cheryl Frederick
Director, Regulatory Affairs
7000 West William Cannon Drive, Building One
Austin, Texas 78735

December 11, 2012

Re: K120791
Trade/Device Name: Ambient™ TurboFlash 90 IFS Wand
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 29, 2012
Received: November 30, 2012

Dear Ms. Frederick:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K120791

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• Ligament	All Joints
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• Meniscal Cystectomy	Knee

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• Rotator Cuff	Shoulder
• Tendon	All Joints
• Wrist Tendons	Wrist

Prescription Use (Part 21 CFR 801 Subpart D) **X** AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number K120791