alpha orthopaedics

K082956

510(k) Summary

Company Information:	Alpha Orthopaedics, Inc. 23575 Cabot Blvd., Ste. 210 Hayward, CA 94545
Contact Information:	Gina To Vice President, Regulatory/Quality Phone: (510) 783-5888 Fax: (510) 783-5889
Date Summary Prepared:	November 5, 2008
Trade Name:	Alpha Orthopaedics AT2 System
Common Name:	Electrosurgical cutting and coagulation device and accessories
Classification:	Product Code GEI, Class II, CFR §878.4400
Predicate Devices (Legally Marketed Device):	• K013639 Thermage ThermaCool TC System • K043402 Thermage ThermaCool System Treatment Tip

DEC 18 2008

DEVICE DESCRIPTION

The AT2™ System consists of a RF generator and accessories, including disposable treatment electrodes.

INTENDED USE

The AT2 System is indicated for use in General Surgical procedures for electrocoagulation and hemostasis.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the AT2 System are same as the Thermage ThermaCool TC System.

SUBSTANTIAL EQUIVALENCE

The AT2 System that is the subject of this notification is substantially equivalent to the predicate legally marketed devices listed above.

SUMMARY OF PERFORMANCE TESTING

Biocompatibility, EMC, safety testing, and software tests have been completed.

CONCLUSION

The technological characteristics and the results of the performance data demonstrate that the Alpha Orthopaedics AT2 System is safe and effective and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alpha Orthopaedics, Inc.
% TÜV SÜD America, Inc.
Ms. Dawn Tibodeau
1775 Old Highway 8 NW / Suite 104
New Brighton, MN 55112-1891

DEC 18 2008

Re: K082956
Trade/Device Name: Alpha Orthopaedics AT2 System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: Class II
Product Code: GEI
Dated: November 26, 2008
Received: December 3, 2008

Dear Ms. Tibodeau:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082956

Device Name: Alpha Orthopaedics AT2 System

Indications for Use:

The AT2™ System is indicated for use in General Surgical procedures for electrocoagulation and hemostasis.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (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 General, Restorative,
and Neurological Devices

510(k) Number K082956