K042690

DEC 1 3 2004

510(k) SUMMARY

SUBMITTER NAME: Ascension Orthopedics, Inc.
8200 Cameron Road, C–140
Austin, TX 78754-3832

CONTACT: Peter Strzepa
Phone: (512) 836-5001
Fax: (512) 836-6933

DATE OF SUMMARY: 28 September 2004

TRADE NAME: Ascension® PyroSphere®

COMMON NAME: carpometacarpal (CMC) implant

CLASSIFICATION: 21 CFR §888.3770

PRODUCT CODE: 87 KYI

PANEL: Orthopedic and Rehabilitation Devices

PREDICATE DEVICE:
Ceramic Zirconia Spherical CMC Implant (K960659)
Ascension PyroHemiSphere (K041451)

DEVICE DESCRIPTION:
The Ascension PyroSphere (PCS) is a single-use, spherical, interpositional prosthesis for the basal thumb joint. It is fabricated from a thick pyrocarbon layer encasing a graphite core that is impregnated with one-atomic percent tungsten so it is radiopaque. The device is available in five sizes and is provided sterile in packaging containing a single component.

INTENDED USE:
The Ascension PyroSphere is intended to replace the joint between the first metacarpal and the trapezium in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis or post fracture deformation or bone loss which present as either a painful, unstable thumb, or a thumb with limited range of motion.

BASIS OF SUBSTANTIAL EQUIVALENCE:
A comparison of the design features as well as performance tests demonstrate that the Ascension PyroSphere is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2004

Mr. Peter Strzepa
Vice President Science and Technology
Ascension Orthopedics, Inc.
8200 Cameron Road, Suite C-140
Austin, Texas 78754

Re: K042690
Trade/Device Name: Ascension® PyroSphere®
Regulation Numbers: 21 CFR 888.3770
Regulation Name: Wrist joint carpal trapezium polymer prosthesis
Regulatory Class: II
Product Code: KYI
Dated: September 28, 2004
Received: September 29, 2004

Dear Mr. Strzepa:

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.

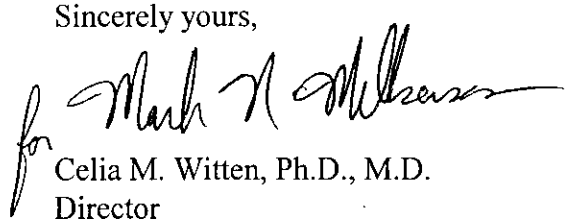
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
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: K042690

Device Name: Ascension® PyroSphere®

Indications for Use:

The Ascension® PyroSphere® is intended to replace the joint between the first metacarpal and the trapezium in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis or post fracture deformation or bone loss which present as either a painful, unstable thumb, or a thumb with limited range of motion.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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