K060560

Page 1 of 1

510(k) SUMMARY

SUBMITTER NAME: Ascension Orthopedics, Inc.
87200 Cameron Road, C–100
Austin, TX 78754-3832

MAY - 5 2006

CONTACT: Glen Neally
Phone: (512) 836-5001 ext 1513
Fax: (512) 836-6933

DATE OF SUMMARY: 28 February 2006

TRADE NAME: Ascension® PyroSphere®

COMMON NAME: pyrocarbon spherical implant

CLASSIFICATION: 21 CFR §888.3730

PRODUCT CODE: KWD

PANEL: Orthopedic

PREDICATE DEVICES:
Orthosphere Ceramic Spherical Implant (K030319)
Ascension® PyroSphere® (K042690)

DEVICE DESCRIPTION:
The Ascension Ascension® PyroSphere™ CMC/TMT is a single-use, spherical, interpositional prosthesis intended for use in the carpometacarpal (CMC) basal thumb joint or the the 4^{th} /5^{th} tarsometatarsal (TMT) joint involvement. It articulates against recesses prepared in the base of the first metacarpal and the trapezium or the tarsometatarsal joint.

INTENDED USE:
The Ascension® PyroSphere™ CMC/TMT) 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.

The Ascension® PyroSphere™ CMC/TMT is also intended for use in the 4^{th} /5^{th} tarsometatarsal (TMT) joint involvement where degenerative or post-traumatic arthritis presents:

- decreased motion
- arthritic changes and/or subluxation
- unstable, stiff, or painful joints
- degenerative joint disease of the midfoot associated with gout or pseudogout

BASIS OF SUBSTANTIAL EQUIVALENCE:
A comparison of the design features as well as performance tests demonstrate that the Ascension® PyroSphere™ CMC/TMT 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

MAY - 5 2006

Ascension Orthopedics, Inc.
Mr. Glen Neally
Vice President of QA/RA/CA
8700 Cameron Road, Suite C-100
Austin, Texas 78754-3832

Re: K060560
Trade/Device Name: Ascension® PyroSphere™ CMC/TMT
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: February 28, 2006
Received: March 2, 2006

Dear Mr. Neally:

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/industry/support/index.html.

Sincerely yours,

for 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: K060560

Device Name: Ascension® PyroSphere™ CMC/TMT

Indications for Use:

The Ascension® PyroSphere™ CMC/TMT 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.

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- decreased motion
- arthritic changes and/or subluxation
- unstable, stiff, or painful joints
- degenerative joint disease of the midfoot associated with gout or pseudogout

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K060560