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Artimplant AB: Artelon CMC Spacer Arthro– K061954

510(k) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes Artimplant AB's summary for the ARTELON CMC Spacer Arthro.

SUBMITTER'S NAME Artimplant AB
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DATE OF SUBMISSION: July 10, 2006

1. **Identification of device**

   Proprietary Name: ARTELON CMC Spacer Arthro
   Common Name: Prosthesis, wrist, carpal trapezium
   Classification Status: Class II per Regulation §888.3770
   Product Code: KYI, wrist joint carpal trapezium polymer prosthesis

2. **Equivalent device**

   ARTELON CMC Spacer, K040070, 09/21/2004.

3. **Description of the Device**

ARTELON CMC Spacer Arthro is a woven textile device made of ARTELON fibres. ARTELON is a biocompatible, degradable material made of polycaprolactone-based polyurethaneurea.

ARTELON CMC Spacer Arthro is designed to act as an interposition part in the joint. The purpose of the vertical portion is to separate the surfaces of the arthritic joint from each other. The purpose of the horizontal portion of ARTELON CMC Spacer Arthro is to fixate the device.

ARTELON CMC Spacer Arthro is a single-use device packaged in double sterile barriers. The ARTELON CMC Spacer Arthro wings are fixed in place using commercially available suture anchors (non-absorbable, diameter approximately 2 mm) in combination with two double-armed class I nonabsorbable USP size 1 sutures.

4. Intended Use

The ARTELON CMC Spacer Arthro is intended to be implanted into the first carpometacarpal joint (CMC-I) as an interpositional spacer between the trapezial bone and the first metacarpal bone.
The device is intended to be used in thumb disabilities caused by osteoarthritis.
This is the **same intended use** as previously cleared for the ARTELON CMC Spacer, K040070.

5. Discussion of Performance Testing

Performance bench testing was utilized needed to demonstrate Substantial Equivalence. The new product met the same release specifications as the previously cleared device. This fact, in conjunction with a comparison of dimensions, materials, basic design, and intended use demonstrated Substantial Equivalence.
A collection of tests have been performed in accordance with:

- ISO 10993 standards
- ISO 14971
- ISO 11137
- ISO 11607
- ISO 11737-1
- AAMI TIR27:2001
- EN868-1

6. Conclusion

The ARTELON CMC Spacer Arthro described in the submission is substantially equivalent to the predicate device, and presents no new concerns about safety and effectiveness. Additionally, the devices have identical indication to the predicate device, and the labeling is consistent both with FDA guidance as well as current medical practice.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Artimplant AB
c/o Ms. Terry Sheridan Powell
Senior Project Manager
M Squared Associates, Inc.
719 A Street, NE
Washington, DC 20002

JUN - 1 2007

Re: K061954
Trade Name: ARTELON CMC Spacer Arthro
Regulation Number: 21 CFR 888.3770
Regulation Name: Wrist joint carpal trapezium polymer prosthesis
Regulatory Class: Class II
Product Code: KYI
Dated: April 24, 2007
Received: May 4, 2007

Dear Ms. Powell:

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.

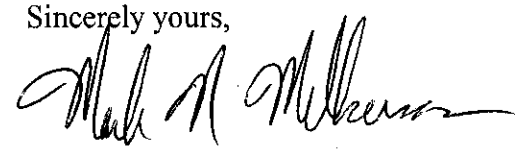
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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):__K061954_____

Device Name: Artelon® CMC Spacer Arthro

Indications for Use:

Artelon® CMC Spacer Arthro intended to be implanted into the first carpometacarpal joint (CMC-I) as an interpositional spacer between the trapezial bone and the first metacarpal bone. The device is intended to be used in thumb disabilities caused by osteoarthritis.

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 K061954