APR - 6 2001

K010124

1 of 3

510(k) Summary

Company: Arthrex, Inc.
Address: 2885 S. Horseshoe Drive, Naples, FL 34104
Phone: (941) 643-5553
Fax: (941) 643-7191

Contact: Vernon C. Brown
Manager of Regulatory Affairs

Trade Name: Arthrex Shoulder Prosthesis
Common Name: Shoulder Prosthesis
Classification: Prosthesis, Shoulder, semi-constrained, metal/polymer cemented
Prosthesis, shoulder, Hemi-, Humeral, metallic uncemented

Description:
The device consists of: a stem body with an angle adapter in the neck section, composed of titanium (Ti6Al4V); a metal head support also of titanium; the prosthesis head composed of Cr-CO alloy, and cemented glenoid components.

Intended Use:
The **Arthrex Shoulder Prosthesis** is indicated for replacement include severe pain or significant disability resulting from degenerative, rheumatoid, or traumatic disease or injury of the glenohumeral joint; ununited humeral head fractures of long duration; irreducible 3- and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.

The glenoid components are designed for cemented fixation in the joint and must only be used with an appropriate bone cement.

Substantial Equivalence:
By definition, substantial equivalence means that a device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and does not raise different questions regarding safety and effectiveness from the predicate device.

The differences between the Arthrex Shoulder Prosthesis and the predicate devices cited do not raise any different questions regarding safety and effectiveness. Furthermore, the materials are well characterized, and have been used in the predicate devices which have nearly identical indications. The device, as designed, is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 6 2001

Mr. Vernon C. Brown
Manager of Regulatory Affairs
Arthrex, Inc.
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K010124
Trade Name: Arthrex Shoulder Prosthesis
Regulatory Class: II
Product Code: KWS and HSD
Dated: January 16, 2001
Received: January 16, 2001

Dear Mr. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

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 Form

510(k) Number (if known): K010124

Device Name: Arthrex Shoulder Prosthesis

Indications for Use:

The Arthrex Shoulder Prosthesis is indicated in replacement(s) when conditions including severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; un-united humeral head fractures of long duration, irreducible 2- and 4- part proximal humeral fractures; avascular necrosis of the humeral head, or other difficult clinical management problems where arthodesis or resectional arthroplasty is not acceptable.

The glenoid components are designed for cemented fixation in the joint and must only be used with an appropriate bone cement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____

(Option Format 1-2-96)

for Mark N Melkerson

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

510(k) Number K010124

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