K965204

510(k) SUMMARY

JUN - 3 1997

Submitter's Name:

Avanta Orthopaedics
9369 Carroll Park Drive, Suite A
San Diego, CA 92121
619-452-8580

Contact: Louise Focht
Date of Preparation: November 1, 1996
Device Name: Avanta Orthopaedics Trapezium Implant
Common Name: Trapezium Implant
Predicate Device: Dow Corning Corporation Silastic Swanson Trapezium Implant

Device Description:

The Avanta Orthopaedics Trapezium Implant is a device intended to be implanted in metacarpal bone of the thumb with resection of the trapezium bone of the wrist. It is made of molded silicone elastomer. The device is intended to be used in the treatment of thumb disabilities because of osteoarthritis, post-traumatic arthritis, or rheumatoid arthritis as follows: Localized pain and palpable crepitation during circumduction movements with axial compression of the thumb. Loss of thumb motion with decrease of normal pinch and grip strength. Radiological evidence of arthritic changes of the trapeziometacarpal joint, trapeziotrapezoid and trapezium second metacarpal joint, singly or in combination.. Unstable, stiff, or painful distal joints of the thumb or swan-neck deformity. Old Bennet fracture.

Comparison of Current Design to Predicate Devices:

Item	*Avanta Product*	*Dow Corning Corporation*
Use	Single use	Single use
Fixation	stem in intramedulary canal	stem in intramedulary canal
Constraint	non constrained	non constrained
Material	Silicone Elastomer	Silicone Elastomer
Sizes	3 sizes, 10, 20, 30	5 sizes 1-5
Indications for use	osteoarthritis, post-traumatic arthritis or rheumatoid arthritis of the trapeziometacarpal joint localized pain and palpable crepitation during circumduction with axial compression of the thumb loss of thumb motion, decrease of normal pinch and grip strength radiological evidence of arthritic changes of the trapeziometacarpal, trapezioscaphoid, trapeziotrapezoid and trapezium second metacarpal joints, singly or in combination unstable, stiff, or painful distal joint of the thumb or swan-neck deformity old Bennett fracture	osteoarthritis, post-traumatic arthritis or rheumatoid arthritis of the trapeziometacarpal joint localized pain and palpable crepitation during circumduction with axial compression of the thumb loss of thumb motion, decrease of normal pinch and grip strength radiological evidence of arthritic changes of the trapeziometacarpal, trapezioscaphoid, trapeziotrapezoid and trapezium second metacarpal joints, singly or in combination unstable, stiff, or painful distal joint of the thumb or swan-neck deformity old Bennett fracture

Similarities of the Avanta Orthopaedics Trapezium Implant and the Dow Corning Corporation Swanson Trapezium Implant include;

Both devices are intended for single use only;
Both devices are intended for surgical implantation longer than 30 days;
Both devices are placed into the metacarpal bone of the thumb and replace the trapezium bone of the wrist;
Both devices are made of industry standard silicone elastomer. No new materials are introduced in either product;
Both devices are comparably sized in diameter;
Both devices have the same indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 1997

Ms. Louise M. Focht
Vice President, Research and Development
Avanta Orthopaedics
9369 Carroll Park Drive, Suite A
San Diego, California 92121

Re: K965204
Trade Name: Avanta Orthopaedics Trapezium Implant
Regulatory Class: II
Product Code: KYI
Dated: March 20, 1997
Received: March 21, 1997

Dear Ms. Focht:

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 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 (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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Intended Use

Avanta Orthopaedics Trapezium Implant may be considered for use in thumb disabilities because of osteoarthritis, post-traumatic arthritis, or rheumatoid arthritis as follows:

- Localized pain and palpable crepitation during circumduction movements with axial compression of the thumb.
- Loss of the thumb motion with decrease of normal pinch and grip strength.
- Radiological evidence of arthritic changes of the trapeziometacarpal joint, trapeziotrapezoid and trapezium second metacarpal joint, singly or in combination.
- Unstable, stiff, or painful distal joints of the thumb or swan-neck deformity.
- Following an old Bennet fracture.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K965201