510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® Total Elbow System

MAY 5 1998

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Osteonics Corporation 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Kate Sutton Regulatory Affairs Specialist
Date of Summary Preparation:	February 6, 1998

Device Identification

Proprietary Name:	Osteonics® Total Elbow System
Common Name:	Total Elbow
Classification Name and Reference:	Elbow Joint Metal/Polymer Semi-Constrained Prosthesis 21 CFR §878.3150

Predicate Device Identification

The Osteonics® Total Elbow System is substantially equivalent to the following competitive and/or Osteonics devices, which have previously been determined substantially equivalent by FDA:

- Osteonics® Linked Semi-Constrained Total Elbow Prosthesis

Device Description

The Osteonics® Total Elbow System, available in right and left versions, is a semi-constrained elbow system that is linked across the joint and achieves fixation to the prepared humerus and ulna through the use of polymethylmethacrylate (PMMA) bone cement. The humeral and ulnar components, which are satin finished, function together through the use of a polyethylene bearing and bushing between the two component surfaces. The axle pin, which is threaded on the lower 3mm to 5mm (depending in implant size chosen) portion of the shaft, fits through the lateral aspect of the humeral component with a polyethylene sleeve (bushing). The axle pin is used to prevent dislocation.

The Osteonics® Total Elbow System components are characterized by the following features:

- A satin finish on the titanium alloy humeral and ulnar components.
- Bearings and bushings manufactured from ultra high molecular weight polyethylene.
- A titanium alloy axle pin which screws directly into the humeral component.

The Osteonics® Total Elbow System differs from the predicate Osteonics® Linked Semi-Constrained Total Elbow Prosthesis in that it features: a) a threaded axle pin that screws directly into the humeral component instead of using a "snap-fit" to lock into a retaining ring; b) it offers a medium size not offered by the predicate, and; c) it offers a longer humeral component, if desired. In all other aspects, the subject device is virtually identical in design and function to the predicate device.

Intended Use:

All components of the Osteonics® Total Elbow System are intended to help restore the normal center of rotation and to duplicate the functional movement of the elbow. The Osteonics® Total Elbow System is comprised of total elbow replacement components which are intended to have maximum contact in the epicondylar regions of the humerus where the highest quality bone is present. The Osteonics® Total Elbow System components are single-use devices. The humeral and ulnar components achieve fixation to the prepared humerus and ulna through the use of polymethylmethacrylate (PMMA) bone cement. The Osteonics® Total Elbow System has been specifically designed to address cases involving rheumatoid and traumatic arthritic conditions, as well as ankylosis involving the elbow.

Indications:

- Painful, disabling joint disease of the elbow resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Distal humeral fracture and/or dislocation.
- Revision of previous unsuccessful total elbow replacement, resurfacing, or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Statement of Technological Comparison:

The substantial equivalence of the Osteonics® Total Elbow System to the predicate device identified above—in terms of intended use, materials, and design features—is based on the following.

Intended Uses:

The intended uses of the subject Osteonics® Total Elbow System are identical to those of the predicate device.

Materials:

Both subject and predicate devices use the identical materials: ASTM F-136-96 titanium alloy (Ti6Al-4V ELI) for the humeral and ulnar components, and the axle pin, and ASTM F-648-96 UHMWPE for the bearings and bushings.

Design:

The design of the Osteonics® Total Elbow System is consistent with that of the predicate Osteonics® Linked Semi-Constrained Total Elbow Prosthesis and differs only in the following:

- The subject device has an axle pin that screw locks into the humeral component instead of employing the snap-fit lock into a retaining ring employed by the predicate device.
- The subject device offers small, medium, and large sizes, whereas the predicate device offers only small and large sizes.
- The subject device offers a total elbow with the option of a longer humeral component.

None of these design differences raise any new questions of safety or effectiveness.

Summary

Based on the similarities presented above, the supporting testing summary, the pre-clinical data incorporated by reference to a prior submission, and the fact that the Osteonics® Total Elbow System components employ standard sterilization and packaging methods, the substantial equivalence of the Osteonics® Total Elbow System to the legally marketed Osteonics® Linked Semi-Constrained Total Elbow Prosthesis is demonstrated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 5 1998

Ms. Kate Sutton
Regulatory Affairs Specialist
Osteonics Corporation
59 Route 17
Allendale, New Jersey 17401-1677

Re: K980502
Trade Name: Osteonics® Total Elbow System
Regulatory Class: III
Product Code: JDC
Dated: February 6, 1998
Received: February 9, 1998

Dear Ms. Sutton:

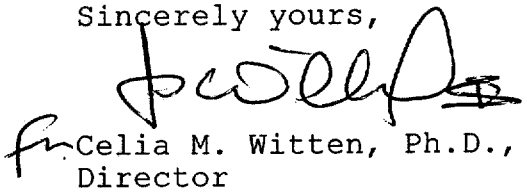
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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 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

510(k) Number (if known): K980502

Device Name: Osteonics® Total Elbow System

Indications For Use:

The indications for the Osteonics® Total Elbow System, in keeping with the legally marketed Osteonics® Linked Constrained Total Elbow Prosthesis, are as follows:

- Painful, disabling joint disease of the elbow resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Distal humeral fracture and/or dislocation.
- Revision of previous unsuccessful total elbow replacement, resurfacing, or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- The Osteonics® Total Elbow System is indicated for cemented use only.

(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 Devices
510(k) Number K980502

Prescription Use X
(Per 21 CFR 801.109)