JUN 10 1998

K981283

510(k) Summary

Device: Rogachefsky Distal Radius Plates

For information contact:

John Dichiara
Director of Regulatory Affairs and Public Policy
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
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Date Prepared: April 16, 1998

Summary:

This submission describes a distal radius plating system including one volar and two dorsal plates (left and right configurations) with a curved profile designed to fit the contour of the distal radius. It is intended for use in internal fixation of fractures of the distal radius. Plates are a modified T shape and are 1.0 mm thick. The plates are manufactured from titanium alloy , Ti 6Al 4V, which conforms to ASTM specification F136. The Rogachefsky Distal Radius Plates are attached to the underlying bone using bone screws previously cleared in the Leibinger Radius Reconstruction Plate System [RRPS] 510(k) submission K961496. The plates are available in sterile and non-sterile versions.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the RRPS Distal Radius Plating System (Howmedica K961496) and the Alta® Tibial/Upper Extremity Plating System Metaphyseal T Plate (Howmedica K885250).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 1998

Mr. John F. Dichiara
Director of Regulatory Affairs and Public Policy
Howmedica Inc.
Pfizer Medical Technology Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K981283
Trade Name: Rogachefsky Distal Radius Plates
Regulatory Class: II
Product Code: HRS
Dated: April 8, 1998
Received: April 8, 1998

Dear Mr. Dichiara:

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

Indications for Use

510(k) Number (if known): K981283

Device Name: Rogachefsky Distal Radius Plates

Indications for Use:

The Rogachefsky Distal Radius Plates are intended for use in internal fixation of fractures of the distal radius.

(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 _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981283