DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vivian Kelly
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
325 Corporate Drive
Mahwah, New Jersey 07430

MAR 3 0 2005

Re: K041709
Trade/Device Name: Numelock™ II System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: June 21,2004
Received: June 23,2004

This letter corrects our substantially equivalent letter of September 8,2004 regarding the incorrect received date of April 23,2004. The correct received date is shown above.

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 (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 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 continue 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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam Provost, Ph.D.
Acting 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): K041709

Device Name: Numelock™ II System

Indications for Use:

The Numelock™ II System is intended for use in the temporary stabilization of long bone fractures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Pan 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K041709

K041709

510(k) Summary of Safety and Effectiveness for the Numelock™ II System

Proprietary Name:	Numelock™ II System
Common Name:	
Classification Name and Reference	Single/multiple component metallic bone fixation appliances and accessories, 87 KTT 21 CFR §888.3030
Regulatory Class:	Class II
Device Product Code:	
For Information contact:	Vivian Kelly, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5581 Fax: (201) 831-6038
Date Summary Prepared:	June 21, 2004

Description:
The Numelock™ II System consists of a series of locking plates and screws for the internal fixation of long bone fractures. The plates are available in different styles and configurations to fit various anatomical sites. Each plate has holes for screw fixation and is pre-contoured to fit the anatomical profile of the different periarticular regions of long bones.

Intended Use:
The Numelock™ II System is intended for use in the temporary stabilization of long bone fractures.

Substantial Equivalence:
The design and function of the Numelock™ II System is substantially equivalent to that of the predicate devices. Both the subject and predicate systems offer different types of plates in varying configurations and lengths for use with the other accessories such as locking screws, shaft screws, and washers. This system is equivalent to other systems on the market in regards to design, materials, indications and operational principals. Mechanical testing demonstrated comparable mechanical properties to the predicate devices.