K033668

MAR 1 1 2004

510(k) Summary

Submitter:	Kinamed, Inc.
Address:	820 Flynn Road Camarillo, CA 93012
Phone number:	(805) 384-2748
Fax number:	(805) 384-2792
Contact person:	Vineet K. Sarin Ph.D.
Date prepared:	November 21, 2003
Trade name:	NaviPro™ Knee Software Module

Substantial equivalence claimed to: 1. OrthoPilot® (K003347) filed by Kinamed Inc.
2. NaviPro™ (K020764) filed by Kinamed, Inc.

Description:
The NaviPro™ Knee Software Module is an extension of the previously cleared NaviPro™ Navigation System. It uses an optical localizing camera and infra-red reflective markers ("trackers") to track the spatial position of bones and medical instruments during knee replacement surgery. Measurements obtained from the system allow for intra-operative assessments of implant position, orientation, and soft-tissue balance.

Intended use:
The NaviPro™ Knee Software Module is an extension of the NaviPro™ Navigation System whose purpose is to measure the spatial orientation of the resection guides and limb alignment during total knee replacement surgery, and for assessing soft tissue balance and changes in the limb mechanical axis as a result of the knee replacement. General spatial measurements may be made and recorded as deemed necessary by the surgeon user.

Summary of technological characteristics:
NaviPro™ Knee intra-operatively reports the position of the tibial and femur resection guides during knee replacement surgery, and measures changes in the mechanical axis of the limb as a result of prosthetic implantation. Pre-operative CT or fluoroscopic imaging is unnecessary. The link between patient and computer is established by infra-red reflective trackers that are securely attached to the patient and surgical instruments. An infra-red localizing camera that is linked to the computer calculates the position and orientation of the trackers.

A calibrated measurement probe is also outfitted with infra-red trackers and can be brought into a spatial relationship with the patient. NaviPro™ Knee requires only the information provided by the trackers and palpated landmarks to determine the spatial orientations of the resection guides, joint centers, and mechanical axis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2004

Mr. Vineet K. Sarin, Ph.D.
Director of Research and Development
Kinamed, Inc.
820 Flynn Road
Camarillo, California 93012

Re: K033668
Trade/Device Name: NaviPro™ Knee Software Module
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: January 23, 2004
Received: January 23, 2004

Dear Dr. Sarin:

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 application (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 such 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 begin 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 (301) 594-4659. 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 C Provost

for 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

(2) Indications for Use

510(k) Number (if known): K033668

Device Name: NaviPro™ Knee Software Module

Indications For Use:

The NaviPro™ Knee Software Module is an extension of the NaviPro™ Navigation System whose purpose is to measure the spatial orientation of the resection guides and limb alignment during total knee replacement surgery, and for assessing soft tissue balance and changes in the limb mechanical axis as a result of the knee replacement. General spatial measurements may be made and recorded as deemed necessary by the surgeon user.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K033668