



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
SILVER SPRING, MARYLAND 20910

MAY 6 1980

Mr. Harry M. Kaufman  
Howmedica, Inc.  
235 East 42nd Street  
New York, New York 10017

Ref: K792089  
Howmedica<sup>R</sup> Kinematic<sup>TM</sup>  
Knee System

Dear Mr. Kaufman:

We have reviewed the additional data submitted March 17, 1980 concerning the Kinematic<sup>TM</sup> Rotating Hinge Knee Prosthesis. Based on this information we have determined the device to be substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. This letter supercedes the January 16, 1980 letter notifying you that the Kinematic<sup>TM</sup> Rotating Hinge Knee Prosthesis is non-equivalent.

You may therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Standards) or Class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practices, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls will be broadened to include additional regulations relating to restricted devices, records and reports, and others.

All regulations and information on meetings of the device classification panels, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, MD 20857.

Received Howmedica

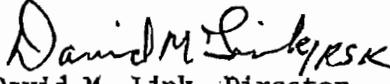
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Regulatory Affairs

Page 2 - Mr. Harry M. Kaufman

This letter should not be construed as approval of your device or its labeling. If you desire advice on the status of labeling for your device or other information pertaining to your responsibilities under the Act, please contact the Bureau of Medical Devices, Division of Compliance Operations, 8757 Georgia Avenue, Silver Spring, MD 20910.

Sincerely yours,

  
David M. Link, Director  
Bureau of Medical Devices

325 Corporate Drive  
Mahwah, NJ 07430

**stryker**<sup>®</sup>

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**Orthopaedics**

**Fax**

To: Aileen Velz-Cabassa  
Fax No.: (301)847-8149  
From: Jan Triani  
Date: March 30, 2010  
Re: K792089  
No. pp. total: 05

Hi Aileen,

As just discussed, here is the SE letter stamped May 6, 1980 for K792089. The 510(k) is not found on the FDA website and I would like to know what I should do to get the submission on the website.

Thank you in advance for your assistance.

Kindest Regards,

  
Jan Triani

P: (201)831-5969  
F: (201)831-4969  
Jan.Triani@stryker.com



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PUBLIC HEALTH SERVICE  
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SILVER SPRING, MARYLAND 20910

JAN 16 1980

**COPY**

Mr. Harry M. Kaufman  
Howmedica, Inc  
235 East 42nd Street  
New York, New York 10017

Received  
Ref: K792089

The Howmedica<sup>R</sup> Kinematic<sup>TM</sup>  
Knee System

Dear Mr. Kaufman:

Regulation

The Food and Drug Administration has completed its review of your premarket notification submission K792089 under Section 510(k) of the Federal Food, Drug, and Cosmetic Act. This submission covers three (3) discrete knee replacement systems: (a) semiconstrained patellofemorotibial (cruciate-retaining) joint prostheses (polymer/metal/polymer), (b) semiconstrained patellofemorotibial (cruciate-sacrificing) joint prostheses (polymer/metal/polymer), and (c) constrained patellofemorotibial joint prostheses (polymer/metal/polymer).

Based on our review of the information that you have submitted, we find the Kinematic Knee Systems A and B to be substantially equivalent.

Based on our review of the information that you have submitted, we find the Kinematic Knee System C not to be substantially equivalent to any device that was in commercial distribution (i.e., constrained patellofemorotibial joint prostheses (polymer/metal/polymer) before May 28, 1976, or to any device introduced since that date which has been classified in Class I (General Controls) or Class II (Performance Standards). This decision is based on: (a) that the Offset Hinge Knee Prosthesis has a metal-to-metal hinge without a rotating stem within a polyethylene sleeve whereas the Kinematic Knee System C has a rotating stem within a polyethylene sleeve; (b) the Noiles Total Knee Prosthesis has a plateau bearing component which helps to distribute forces transmitted through the hinge pin and its bearing while the Kinematic Knee System C does not have this plateau bearing component; and (c) the upper surface of the tibial sleeve in the Noiles design has a stepped-up stop to prevent uncontrolled rotation of the tibial stem within the sleeve whereas the Kinematic Knee System C does not. In addition, we are not aware that the Noiles Total Knee was in commercial distribution prior to May 28, 1976.

Premarket Approval. Section 515(a)(2) of the Act requires Class II devices to have an approved premarket approval application before they can be legally marketed, unless the device is the subject of an investigational device exemption under Section 520(g) or unless the device has been reclassified.

Page 2 - Mr. Kaufman

Investigational Use. In the absence of an approved premarket approval application, a Class II device may be distributed only for investigational use. Enclosed, for your review and information, is the proposed regulation for investigational devices which was published in the FEDERAL REGISTER on May 12, 1978. After the regulation becomes effective, a device may be distributed for investigational purposes only if it complies with these regulations. In the meantime, we suggest that you follow these proposed regulations if you wish to ship the device for investigational purposes. We believe the regulations set forth desirable procedures and safeguards for the conduct of clinical investigations. The label for such devices must indicate that the devices are for investigational use only.

Petition for Reclassification. If you believe that your device should not have to undergo premarket approval before it is commercially distributed, you may petition FDA for reclassification of your device under Section 513(f)(2) of the Act.

Premarket approval applications, investigational device exemption requests, and petitions for reclassification should be submitted to:

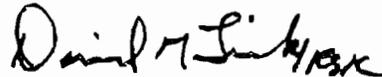
Food and Drug Administration  
Bureau of Medical Devices  
Document Control Center (HFK-20)  
8757 Georgia Avenue  
Silver Spring, Maryland 20910

Any commercial distribution of this device prior to approval of an application for premarket approval or the effective date of an order by the FDA reclassifying your device into Class I or II, would be a violation of the Federal Food, Drug, and Cosmetic Act.

Should you require any additional information concerning our decision or the alternatives available to you under the law, please contact:

Robert S. Kennedy, Ph.D.  
Associate Director for  
Device Evaluation (HFK-400)  
Bureau of Medical Devices

Sincerely yours,



David M. Link, Director  
Bureau of Medical Devices

Enclosure