510(k) Premarket Notification Database

Device Classification Name	Lavage, Jet
510(K) Number	K926337
Regulation Number	880.5475
Device Name	BONE LAVAGE SYSTEM
Applicant	INNOVATIVE SURGICAL DEVICES CORP. 413 S. Martha St. Stillwater, MN 55082
Contact	Karen M Roche
Classification Product Code	FQH
Date Received	12/17/1992
Decision Date	06/11/1993
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General Hospital
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary/Purged 510(K)
Type	Traditional
Reviewed By Third Party	No

Database Updated 2/06/2006

INNOVATIVE SURGICAL DEVICES CORPORATION
9299 NEAL AVENUE NORTH
STILLWATER MN 55082

March 5, 1999

Food & Drug Administration
Center for Devices and Radiological Health, Office of Device Evaluation
Document Mail Center HFZ 401
1390 Piccard Drive
Rockville MD 20850

Re: 510(k) Number K926337

Dear Sirs:

I am writing to notify you that Innovative Surgical Devices Corporation has recently granted an exclusive license to Kinamed, Inc., to the technology covered by 510(k) Number K926337, known as the CarboJet Bone Lavage System.

Kinamed is assuming all rights and responsibility for manufacturing and distribution of the device.

Thank you.

Sincerely,

Karen M. Roche
President

cc: Kinamed, Inc.
2192-C Anchor Court
Newbury Park CA 91320

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JUN 11 1993

Ms. Karen M. Roche
President
Innovative Surgical Devices Corporation
413 South Martha Street
Stillwater, Minnesota 55082

Re: K926337
Bone Lavage System
Regulatory Class: II
Dated: November 30, 1992
Received: December 17, 1992

Dear Ms. Roche:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the

labeling for your device please contact the Division of Compliance Operations, Device Labeling Compliance Branch (HFZ-326) at (301) 427-1342. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Paul R. Beninger, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health