

SUMMARY OF SAFETY AND EFFECTIVENESS**DISPOSABLE IRRIGATION BIPOLAR CORD ASSEMBLY
for Malis™ System CMC®-II**

The *Disposable Irrigation Bipolar Cord Assembly* is a single-use product sold sterile, and is intended for use with standard bipolar irrigating forceps, and the Codman & Shurtleff, Malis™ CMC®-Bipolar System. This device is to be used to deliver electrical energy from a *Malis™ CMC®-III (or equivalent) Generator* to the bipolar irrigating forceps (handpiece), as well as, provide the system with an integrated delivery conduit, for carrying an irrigating solution from its collapsible reservoir to the forceps, via gravity feed.

Biological safety will be assured through the selection of irrigating lumen materials, which demonstrate appropriate levels of biocompatibility. The materials will be tested in accordance with ISO Standard 10993-1, Biological Evaluation of medical devices, part 1 (external communicating device, blood path indirect, contact duration category "A").

Sterilization safety will be assured to a sterility assurance level (SAL) of 10^{-6} . Sterility will be validated in accordance with, and in compliance with the requirements of the applicable sections of the following standards:

- AAMI / ISO 11137 (current edition) *Sterilization of health care products-requirements for validation and routine control-radiation sterilization*, and,
- EN 552 (current edition) *Sterilization of medical devices – Validation and routine control of sterilization by irradiation*.

Performance safety will be assured via testing in accordance with, and in compliance with the requirements of the applicable sections of the following standards;

- IEC 601-1-2 (1988), Medical Electrical Equipment Part 1; General Requirements for the Safety.
- IEC 601-2-2 (1991), Medical Electrical Equipment Part 2; particular Requirements for the safety of High Frequency Surgical Equipment.
- ANSI/AAMI HF 18 (1993), American National Standard for Electrosurgical Devices

The *Disposable Irrigation Bipolar Cord Assembly* is substantially equivalent in function and intended use to both the;

- 80-1163, *Malis™ Integrated Irrigation Tubing and Bipolar Cord Set*, and
- NU1060, *Irrigation / Bipolar Set, for Malis System CMC-II*

™ Malis is a trademark of Leonard I. Malis, M.D.

® CMC is a registered trademark of Johnson & Johnson Professional, Inc.

Kirwan Surgical Products, Inc.
Marshfield, MA 02050



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1999

Mr. Kevin P. Prario
Regulatory Affairs Manager
Kirwan Surgical Products, Inc.
180 Enterprise Drive
P.O. Box 427
Marshfield, Massachusetts 02050

Re: K992218
Trade Name: Disposable Irrigation Bipolar Cord Assembly
Regulatory Class: II
Product Code: GEI
Dated: June 30, 1999
Received: July 1, 1999

Dear Mr. Prario:

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.

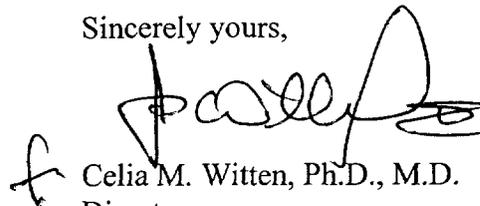
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Mr. Kevin P. Prario

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) 594-4595. 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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

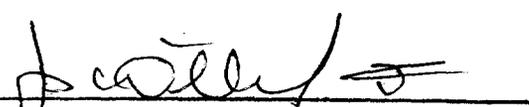
510(k) Number (if known): K 992218

Date: 6/30/99

Device Name: Disposable Irrigation Bipolar Cord Assembly for Malis™ System CMC®-II

Indications For use:

The *Disposable Irrigation Bipolar Cord Assembly* is a single-use product sold sterile, and is intended for use with standard bipolar irrigating forceps, and the Codman & Shurtleff, Malis™ CMC®-Bipolar System. This device is to be used to deliver electrical energy from a *Malis™ CMC®-III (or equivalent) Generator* to the bipolar forceps (handpiece), as well as, provide the system with an integrated delivery conduit, for carrying an irrigating solution from its collapsible reservoir to the forceps, via gravity feed.



(Division Sign-Off)
Division of General Restorative Devices K 992218
510(k) Number K 992218

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

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)