

NIR™ Biliary Stent

August 22, 1997

ATTACHMENT H

SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation choose to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the proposed NIR™ Biliary Stent is as follows:

Trade Name: NIR™ Biliary Stent

Manufacturer: Boston Scientific Corporation/ Ireland (BSIL)
Galway, Ireland

Device Generic Name: Biliary Stent

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices: Johnson & Johnson Palmaz™ Biliary Stent
BSC Symphony™ Transhepatic Biliary Stent System

All of the devices mentioned above have been determined substantially equivalent by FDA.

Device Description:

The proposed NIR™ Biliary Stent is a balloon expandable stent designed to be used with a balloon dilatation catheter. The delivery catheter facilitates transhepatic access to the biliary tree and the stent is designed to maintain luminal patency of biliary strictures produced by malignant neoplasms.

Safety and Performance:

Functional and integrity bench testing and Biocompatibility testing (according to the FDA guidance document, ODE Blue Book Memorandum #G95-1, May 1, 1995, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing") were performed, and the data supported the substantial equivalence of the NIR™ Biliary Stent to the predicate devices.

Conclusion:

Based on the Indications for Use, technological characteristics and safety and performance testing, the NIR™ Biliary Stent has been shown to be safe and effective for its intended use.

NOV 13 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Ms. Tami Abudi
Clinical Research and Regulatory Affairs
Medinol Ltd.
POB.58165
Kiryat Atidim, Bldg. 3
Entrance 2, 4th Floor
Tel Aviv 61581 ISRAELRe: K973171
NIR™ Biliary Stent
Dated: August 11, 1998
Received: August 17, 1998
Regulatory Class: II
21 CFR 876.5010/Procode: 78 FGE

Dear Ms. Tami Abudi:

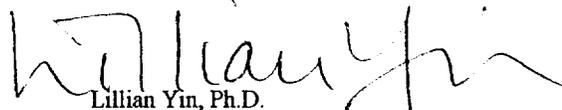
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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.

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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): New Application

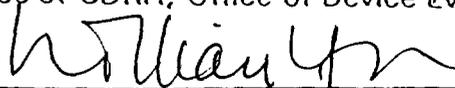
Device Name: NIR Biliary Stent System

Indications For Use:

The NIR Biliary Stent is indicated for use in the treatment of biliary strictures produced by malignant neoplasms.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K993171/S⁰⁸¹

Prescription Use
(Per 21 CFR 201.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)