AUG 1 7 2001

K012216
Page 1 of 2

## Section 4 — Summary of Safety and Effectiveness

**(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)**

### II. General Provisions

| | |
|---|---|
| Submitter's Name and Address | Boston Scientific Scimed, Inc.<br>One Scimed Place<br>Maple Grove, Minnesota 55311 |
| Contact Person | Candice Burns<br>(763) 494-2845 |
| Classification Name | Biliary Catheter and Accessories<br>Product Code – 78 FGE<br>Regulation Number – 876.5010 |
| Common or Usual Name | Biliary Stent |
| Proprietary Name | NIROYAL® Biliary Premounted Stent System |
| Name of Predicate Devices | NIROYAL® Biliary Premounted Stent System |

### III. Device Description

The NIROYAL® Biliary Premounted Stent System (NIROYAL® Biliary System) is a stent system consisting of a 0.018" balloon delivery catheter and a gold plated stainless steel stent. The modified NIROYAL® Biliary System is the same as the NIROYAL® Biliary System cleared under K003929, with the exception of the delivery balloon size for the 7 mm x 14 mm stent. The 7 mm x 14 mm stent will be mounted on a 20 mm balloon, instead of a 15 mm balloon as described in K003929.

### IV. Intended Use

The NIROYAL® Biliary System is indicated for use in the treatment of biliary strictures produced by malignant neoplasms.

### V. Summary of Technological Characteristics

Same as the NIROYAL® Biliary System cleared under K003929.

### VI. Non-Clinical Test Summary

Functional testing was conducted to verify the integrity of the modified balloon length of 20 mm for the 7 mm x 14 mm NIROYAL® Biliary System.

K012214
Page 2 of 2

## Section 4 Summary of Safety and Effectiveness (cont.)

### IV. Non-Clinical Test Summary (cont.)

The functional testing included:

| Test | Acceptance Criteria |
|---|---|
| Tracking Force | 1.5 lbf maximum |
| Stent Deployment Pressure | 103 psi maximum |
| Balloon Burst Pressure Within the Stent | 176 psi minimum |
| Stent Profile | 0.075" maximum |
| Stent Expansion Uniformity at Nominal and Rated Pressure | 5% maximum |
| Stent Foreshortening at Nominal and Rated Pressure | 20% maximum |
| Balloon Burst Pressure Out of the Stent | 176 psi minimum |
| Stent Securement | 0.30 lbf minimum |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 7 2001

Ms. Candice Burns
Regulatory Affairs Specialist
Boston Scientific SCIMED
One Scimed Place
MAPLE GROVE MN 55311-1566

Re: K012216
NIROYAL® Biliary Premounted Stent System
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: July 13, 2001
Received: July 16, 2001

Dear Ms. Burns:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

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.

The 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. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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, 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,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K012216

Device Name: NIROYAL® Biliary Premounted Stent System

FDA's Statement of the Indications For Use for device:

The NIROYAL® Biliary Premounted Stent System is indicated for use in the treatment of biliary strictures produced by malignant neoplasms.

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012216