

OCT 9 2003

K032768



**Medtronic**

**510(k) Summary for the Medtronic, Inc. RACER Biliary Stent System**

<b>510(k) Summary</b>	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.
<b>Submitter</b>	Medtronic, Inc. Peripheral Technologies 3576 Unocal Place Santa Rosa, California 95407
<b>Contact Person</b>	Sarah Sheppard Regulatory Affairs Manager Peripheral Technologies Phone: (707) 591-7465 FAX: (707) 591-7406 e-mail: <a href="mailto:sarah.sheppard@medtronic.com">sarah.sheppard@medtronic.com</a>
<b>Date Prepared</b>	September 5, 2003
<b>Trade Name</b>	Medtronic, Inc. RACER Biliary Stent System ("RACER")
<b>Common Name</b>	Biliary Stent and Delivery System
<b>Classification Name</b>	Biliary Catheter and Accessories
<b>Device Classification</b>	Classification: Class II Classification Panel: 78FGE Regulation Number: 21 C.F.R. §876.5010
<b>Predicate Device</b>	Bridge Constant Biliary Stent System (K030633) (Previously named Bridge Symbiant)
<b>Performance Standards</b>	Performance standards have not been established by the FDA under section 514 of the Federal, Food, Drug and Cosmetic Act

## 510(k) Summary for the Medtronic, Inc. RACER Biliary Stent System

<b>Device Description</b>	The RACER Biliary Stent System consists of a MP35N (Cobalt, Nickel, Chromium, Molybdenum Alloy) stent mounted on an over-the-wire delivery system. The device is equipped with an AV100 balloon mounted on the distal portion of the catheter. Diameters of the device include 4.0, 5.0, 6.0, and 7.0mm and the lengths are either 12mm or 18mm, all premounted on 80cm or 130cm catheters.
<b>Indications for Use</b>	The RACER Biliary Stent System is indicated for use in the palliation of malignant neoplasm in the biliary tree.
<b>Technological Characteristics</b>	The RACER Biliary Stent System is substantially equivalent to the currently cleared Bridge Constant Biliary Stent System (K030633). The subject and predicate stents are identical both in material and technology and are intended for palliation of malignant neoplasms in the biliary tree. The subject and predicate stents are constructed from identical biocompatible materials. The subject and predicate stents are both balloon expandable and premounted on a sheathless delivery system. The subject device offers a lower crossing profile. The subject and predicate stents are both intended to meet clinical needs. The difference between the subject and predicate devices are minor and are not relevant to the ability of the subject device to palliate malignant neoplasms in the biliary tree.
<b>Nonclinical Performance</b>	Preclinical testing was conducted to confirm the safe and effective performance of this device as well as the biocompatibility of the device.
<b>Sterilization</b>	The RACER Biliary Stent System is provided sterile. The device is not intended for reuse or resterilization.
<b>Conclusion</b>	The RACER Biliary Stent System is substantially equivalent to the currently cleared Bridge Constant device (K030633) and meets the clinical needs of the physicians.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Sarah Sheppard  
Regulatory Affairs Manager  
Peripheral Technologies  
Medtronic AVE  
3576 Unocal Place  
SANTA ROSA CA 95403

Re: K032768

Trade/Device Name: Medtronic, Inc. RACER Biliary Stent System  
Regulation Number: 21 CFR §876.5010  
Regulation Name: Biliary catheter and accessories  
Regulatory Class: II  
Product Code: 78 FGE  
Dated: September 5, 2003  
Received: September 9, 2003

Dear Ms. Sheppard:

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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

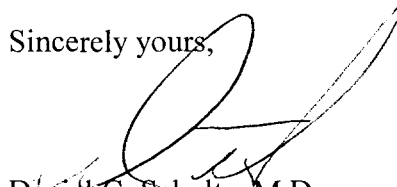
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Section 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 Part 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 Part 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,



Daniel G. Schultz, M.D.

Director

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032768

Device Name: Medtronic, Inc. RACER Biliary Stent System

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

The Medtronic, Inc. RACER Biliary Stent System is indicated for use in the palliation of malignant neoplasms in the biliary tree.

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 K032768