

510(k) NOTIFICATION SUMMARY

Medtronic InStent EsophaCoil Esophageal Stent System
and EsophaCoil Proximal and Distal Extension Systems

A. General Provisions

Submitter's Name Medtronic InStent
Submitter's Address 6271 Bury Drive
 Eden Prairie, Minnesota 55346
Contact Person John R. Dalpee
 Senior Quality Assurance/Regulatory Affairs
 Manager
Classification Name: Esophageal Endoprosthesis 21 CFR Part 878.3610
Common or Usual Name: Esophageal Endoprosthesis
Proprietary Name: EsophaCoil Esophageal Stent System
 EsophaCoil Proximal and Distal Extension Systems

B. Name of Predicate Device

These devices are considered substantially equivalent to the Medtronic InStent EsophaCoil Esophageal Stent System. (K944187 and K955041)

C. Device Description

The Medtronic InStent EsophaCoil Esophageal Stent is a self-expanding, tightly wound spiral Nitinol wire coil which is flared at both ends to enhance fixation. The EsophaCoil Extension is identical to the EsophaCoil Esophageal Stent except that only one end is flared. The non-flared end of the EsophaCoil Extension is inserted into an implanted esophageal stent to extend the length of the stent. The delivery catheter is identical to the currently marketed device. The variable release handle utilizes three independently sliding levers located on the catheter's proximal end that can release the stent in any sequence order; distal release, center release, or proximal release depending upon which of the sliding levers is pulled first, second, or third.

D. Intended Use

The Medtronic InStent EsophaCoil Esophageal Stent System is intended for use in the treatment of esophageal obstructions produced by malignant neoplasms.

The Medtronic InStent EsophaCoil Proximal and Distal Extensions are intended for extending previously placed esophageal stents exhibiting tumor overgrowth or tumor ingrowth on the upper or lower portion of the existing stent respectively.

E. Summary of Technological Characteristics

The modified EsophaCoil Esophageal Stent is identical to the currently marketed device with the exception of the surface preparation. The EsophaCoil Extension Systems are identical to the currently marketed device with the exception that the EsophaCoil Extension has only one flared end, rather than two flared ends as in the EsophaCoil Esophageal Stent.

F. Non-Clinical and Clinical Test Summary

Corrosion testing was performed to evaluate the safety of the device. No other testing was deemed necessary for the new or modified devices.

G. Conclusions

Based on the testing performed and the nature of the changes, it was concluded that the modified devices are substantially equivalent to the currently marketed device. The construction, materials packaging and sterilization methods

H. Other Information

No other information was deemed necessary for the determination of substantial equivalence of the EsophaCoil Esophageal Stent modifications or the new models, the EsophaCoil Distal and Proximal Extension Systems.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 1998

Mr. John R. Dalpee
Senior Quality Assurance/Regulatory Affairs Manager
Medtronic InStent
6271 Bury Drive
Eden Prairie, Minnesota 55346

Re: K973584
Trade Name: Medtronic InStent EsophaCoil Esophageal Stent System and
EsophaCoil Extension System
Regulatory Class: III
Product Code: EWZ
Dated: September 19, 1997
Received: September 22, 1997

Dear Mr. Dalpee:

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.

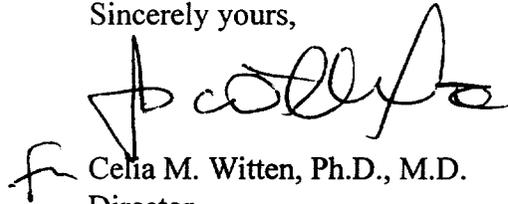
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title-21, Parts 800 to 895. A substantially 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) 594-4595. 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". The signature is written in a cursive style with a large initial "C" and "W".

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): K973584

Device Name: Medtronic InStent EsophaCoil Esophageal Stent System and EsophaCoil Extension System

Indications For Use:

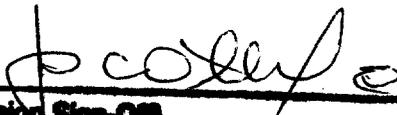
The Medtronic InStent EsophaCoil Esophageal Stent System is intended for use in the treatment of esophageal obstructions produced by malignant neoplasms.

The Medtronic InStent EsophaCoil-Distal Extension System is intended for use in extending previously implanted esophageal stents exhibiting tumor overgrowth on the distal side of the stent.

The Medtronic InStent EsophaCoil Proximal Extension System is intended for use in extending previously implanted esophageal stents exhibiting tumor overgrowth on the proximal side of the stent.

(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 General Restorative Devices
510(k) Number K973584

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)