DEC 18 1998

K985297

510(k) NOTIFICATION AND SUMMARY

Medtronic InStent EsophaCoil Esophageal Stent System with Slow Release

A. General Provisions

Submitter's Name	Medtronic InStent
Submitter's Address	6271 Bury Drive Eden Prairie, Minnesota 55346
Contact Person	Noel Messenger Vice President, Regulatory Affairs
Classification Name	Esophageal Endoprosthesis 21 CFR, Part 876.3610
Common or Usual Name	Esophageal Endoprosthesis
Proprietary Name	EsophaCoil Esophageal Stent System with Slow Release

B. Name of Predicate Device

EsophaCoil Esophageal Stent System and Variable Release
K941487 and K955041 respectively

C. Device Description

The Medtronic InStent EsophaCoil Esophageal Stent System with Slow Release is self-expandable metal stent which is mounted on a delivery catheter. The stent is manufactured from a nickel titanium (Nitinol) material and is comprised of a center stenting section of adjacent coils and two flared ends which enhance fixation. The delivery catheter is manufactured from a thermoplastic material with a tapered end and flexible tip. The stent is wound in a reduced diameter configuration and held in place by a restraining means. The restraining means in connected to the "slow release" handle on the proximal end of the catheter. The slow release allows the stent to be released from the catheter in a fixed and controlled speed manner.

D. Intended Use

The Medtronic InStent EsophaCoil Esophageal Stent System with Slow Release in indicated for use in the treatment of esophageal obstructions produced by malignant neoplasms.

E. Summary of Technological Characteristics

The modified EsophaCoil Stent System with Slow Release is identical to the currently marketed EsophaCoil Stent System with Variable Release with the exception of the slow release modification. The modified slow release handle allows a fixed, controlled (slower) release sequence, where the variable release allowed the stent to be released in which ever sequence was desired by the physician without the slower control mechanism.

F. Non-Clinical and Clinical Test Summary

Testing was performed to evaluate the safety and effectiveness of the slow release mechanism. No other testing was deemed necessary for the modification of this device.

G. Conclusions

Based on the testing performed and the nature of the change, it was concluded that the modified device is substantially equivalent to the currently marketed device.

H. Other

No other information was deemed necessary for the determination of substantial equivalence of the EsophaCoil Stent System with Slow Release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 1998

Mr. Noel Messenger
Vice President Regulatory Affairs
Medtronic InStent
6271 Bury Drive
Eden Prairie, Minnesota 55346

Re: K983297
Trade Name: EsophaCoil Esophageal Stent System with Slow Release
Regulatory Class: II
Product Code: ESW
Dated: September 4, 1998
Received: September 21, 1998

Dear Mr. Messenger:

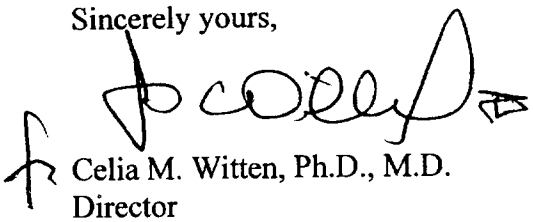
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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,



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

K983297

510(k) Number (if known):_____

Device Name: EsophaCoil Esophageal Stent System with Slow Release

Indications For Use:

The EsophaCoil Slow Release esophageal prosthesis is indicated for use in the treatment of esophageal obstructions 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)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983297