510(k) SUMMARY of Safety and Effectiveness

I. Applicant Information:

MAY - 7 2008

Date Prepared:	April 14, 2008
Submitter:	Medtronic, Inc.
Address:	710 Medtronic Parkway, NE Minneapolis, MN 55432-5604
Establishment Registration No.	2135394
Contact Person:	David D. Cox, Ph.D. Regulatory Consultant
Telephone Number:	(651) 247-7900
Fax Number:	(763) 391-9259

II. Device Information:

Trade Name:	U-CLIP™ Uni-Fire
Common Name:	Implantable clip
Classification Name:	Clip, Implantable
Classification:	Class II, 21 CFR 878.4300
Product Code:	FZP
Predicate Device:	Medtronic U-CLIP™, Model NC65 510(k) No. K062057, Reg. No. 878.4300; Product Code: FZP

Device Intended Use: The U-CLIP™ device is intended for endoscopic and non-endoscopic general soft tissue and prosthetic material approximation/attachment and/or ligation and the creation of anastomosis in blood vessels, grafts and other tubular structures; including cardiovascular and coronary artery bypass grafting procedures; including use in cardiovascular and coronary artery bypass grafting procedures.

U-CLIP™ Uni-Fire, Model M65

Device Description:	The U-CLIP™ is a self-closing clip for anastomosis and tissue and prosthetic material approximation or attachment applications. The Model M65 U-CLIP™ Uni-Fire device consists of a self-closing Nitinol clip that is constrained in an open position in a stainless steel hypotube until released by the surgeon after placement. The clip is released from a slot in the side of the hypotube. After release, the arms of the clip attempt to regain their preferred, closed configuration, thereby holding the tissue layers together. This design allows precise placement of clips prior to closure, and facilitates an interrupted "suture" technique by eliminating knot tying. The device is manufactured with a standard implantable grade of Nitinol.
Intended Use:	The U-CLIP™ Uni-Fire is intended for endoscopic and non-endoscopic general soft tissue and prosthetic material approximation/attachment and/or ligation and the creation of anastomosis in blood vessels, grafts and other tubular structures; including use in cardiovascular and coronary artery bypass grafting procedures.
Contraindications:	Do not use for tubal ligation.
Comparison to Predicate Device(s):	The U-CLIP™ Uni-Fire device is substantially equivalent to the U-CLIP™ Model NC65 device cleared in K062057 and other U-CLIPs cleared in K31623, K024366, K060400, K023125, K021407, K013664, K012317, K994160, and K971588 in terms of materials, use and application. The new clip is released from the side of the hypotube, just like the predicate device, but it has a flattened end to allow it to be mechanically held prior to release. The new clip is made of the same Nitinol alloy, with the same wire diameter, overall length and closed clip diameter as the predicate device.
Test Data:	Verification and validation testing confirms that functional characteristics are substantially equivalent to the predicate device cited. This included clip strength and clip deployment. All test data obtained satisfied the documented product and performance specifications.
Summary:	Based upon the technical information, intended use, *in vitro*, *in vivo*, and clinical performance information provided in previous pre-market notifications, the U-CLIP™ Uni-Fire, Model M65 described in this submission has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2008

Medtronic, Inc.
% Innovatrix, Inc.
David D. Cox, Ph.D.
3051 S. Newcombe Way
Lakewood, Colorado 80227

Re: K081082
Trade/Device Name: U-CLIP® Uni-Fire, Model M65
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP
Dated: April 14, 2008
Received: April 16, 2008

Dear Dr. Cox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

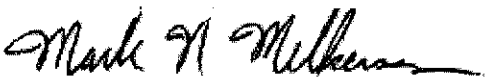
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081082

Device Name: **U-CLIP® Uni-Fire, Model M65**

Indications for Use:

The U-CLIP™ Uni-Fire is intended for endoscopic and non-endoscopic general soft tissue and prosthetic material approximation/attachment and/or ligation and the creation of anastomosis in blood vessels, grafts and other tubular structures; including use in cardiovascular and coronary artery bypass grafting procedures.

Prescription Use X AND/OR Over-the-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Pogue for mrm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081082