

FEB - 7 2005

**4. 510k Summary**

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This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87.

Establishment Registration Number: 2021898

Address of Manufacturer: Medtronic Neurosurgery  
125 Cremona Drive  
Goleta CA, 93117  
(805) 968-1546 ext. 1773  
Fax: (805) 968-9336

Contact Person: Jeffrey Henderson

Date: January 6, 2005

Trade or Proprietary Name: Medtronic Clip Gun Kit

Common usual or Classification Name: Dispensing Gun; Raney Type  
Scalp Clips ( 882.4150)

Predicate Device Identification: Clip Gun with Raney Type Scalp Clips (K896723)

Description: The Clip Gun Kit contains Raney-type clips intended to provide hemostasis during cranial surgery by preventing arterial bleeding from vessels under the scalp. The Clips are a non-implantable transient use device.

Intended Use: The Medtronic Neurosurgery Clip Gun Raney-type clips provide hemostasis during cranial surgery by preventing arterial bleeding from small vessels of the skin and deeper vessels under the scalp.

Intended Use of predicate device(s): The Clip Gun utilizes standard Raney-type scalp clips to provide hemostasis for craniotomy.

Technological comparison: Medtronic Neurosurgery submits that the materials of fabrication, intended use, performance characteristics and design specifications of the Clip Gun Kit are the same as the previously reviewed and cleared Clip Gun with Raney Type Scalp Clips. Based upon the summary above, Medtronic Neurosurgery determines substantial equivalence, safety, and efficacy of the Clip Gun Kit products based upon the predicate and currently marketed devices.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Jeffrey Henderson  
Vice President, Quality  
and Regulatory Affairs  
Medtronic Neurosurgery  
125 Cremona Drive  
Goleta, California 93117

Re: K050044

Trade/Device Name: Clip Gun Kit  
Regulation Number: 21 CFR 882.4150  
Regulation Name: Scalp Clip  
Regulatory Class: II  
Product Code: HBO  
Dated: January 6, 2005  
Received: January 19, 2005

Dear Mr. Henderson:

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.

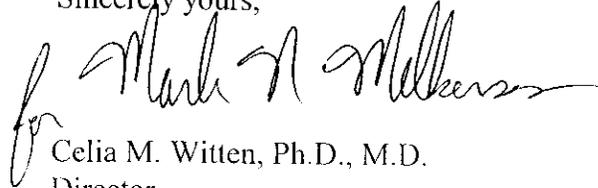
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Mr. Jeffrey Henderson

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive style and is positioned above the typed name.

Celia M. Witten, Ph.D., M.D.  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

Device Name: Clip Gun Kit Special 510(k) Number (if known): K050044

Indications for Use:

The Medtronic Neurosurgery Clip Gun Raney-type clips provide hemostasis during cranial surgery by preventing arterial bleeding from small vessels of the skin and deeper vessels under the scalp.

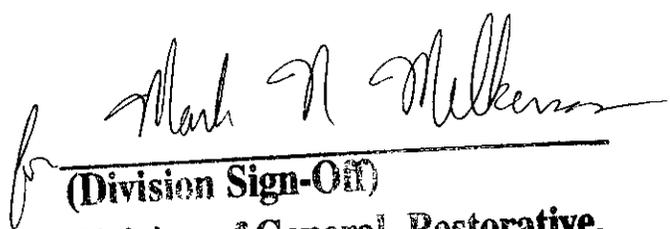
Over the Counter Use:

or

Prescription Use:   
(Per 21 CFR 801.109)

(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,**  
**and Neurological Devices**

510(k) Number K050044