K050044

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4. 510k Summary

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2005

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.

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,

for 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: X
(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)

for Mark N Milhern

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

510(k) Number K050044