SEP - 9 2003

K032238 P1/2

Premarket Notification 510(k) Submission
Neurosel (Medical) Ltd. Twister™

510(k) Summary

July 11th 2003

1 Submitter

Neurosel (Medical) Limited
Greenways
Abbotts Ann
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United Kingdom

Contact: Prof. Peter Gibson
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2 Name of Device

Proprietary Name: Twister™ Superelastic Ligating Clip and Applier, Size M

Common Name: Clip, Implantable

Device Classification: Implantable Clips have been placed in Class II as per 21 CFR Regulation Number 878.4300 and assigned the Product Code FZP

3 Predicate Devices

The Twister™ Superelastic Ligating Clip and Applier is substantially equivalent to the following legally marketed devices:

K830503	Ethicon Ligaclip® Titanium Ligating Clip
K864102	Ethicon Ligaclip® 20/20 Multiple Clip Applier

4 Device Description

The Twister™ Superelastic Ligating Clip System comprises a dedicated applier containing a number of Twister™ Superelastic Ligating Clips held in-train in an un-stretched state. The applier consists of a front nozzle, handle and main body with a trigger. The clips are applied by a two stage trigger activation process of the applier; in the first step the clip is advanced and stretched to an open position, and in the

second step the clip is released into position on the vessel or structure to be ligated. Prior to activation, the applier nozzle design allows for assessment of the suitability of a particular clip size in relation to that of the blood vessel, or other body tubular structure. Surgeons should only apply an appropriately sized clip for the size of vessel or tissue structure to be ligated, such that the clip completely encompasses the vessel or tissue structure. The specific nozzle design is intended to assist the surgeon in optimal clip application, by virtue of its shape and external guide markings.

The Twister™ clip is manufactured from a Superelastic Nitinol alloy, which has a shape memory effect. During application of the Twister™ clip, the clip is opened for placing over the vessel or structure. On its release from the applier, the Twister™ clip resumes its original 'shape memory' closed position, and its arms encircle the vessel or structure – effectively ligating the vessel or structure by applying a pressure.

The Twister™ clip and its applier are single use medical devices and both the applier and any remaining unused clips should be discarded following the surgical procedure The Twister applier and clips are not intended for re-sterilization.

5 Intended Use

The Twister™ Superelastic Ligating Clip, Size M, and its applier is intended for the permanent occlusion or ligation of blood vessels and other tubular body structures, wherever a metal ligating clip is indicated, and within the size range of 2.0 to 3.5mm diameter.

6 Summary of Substantial Equivalence

The Twister™ Superelastic Ligating clip and applier is similar in design, intended use and performance characteristics to the predicate devices. There are no new issues of safety of effectiveness raised by the subject device. Differences between the subject device and the predicate devices were the subject of laboratory and animal studies to establish safety and effectiveness. The biocompatibility of the materials used in the subject device has also been established.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2003

Professor Peter Gibson
Neurosel (Medical) Limited
Greenways
Abbotts Ann
Andover, Hampshire
United Kingdom SP11 7BH

Re: K032238
Trade/Device Name: Twister™ Superelastic Ligating Clip and Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: II
Product Code: FZP
Dated: July 17, 2003
Received: July 21, 2003

Dear Professor Gibson:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Indications for Use Statement

Ver/3 - 4/24/96

Applicant: Neurosel (Medical) Ltd.

510(k) Number (if known):

Device Name: Twister™ Superelastic Ligating Clip and Applier

Indications For Use:

The Twister™ Superelastic Ligating Clip, Size M, and its applier is intended for the permanent occlusion or ligation of blood vessels and other tubular body structures, wherever a metal ligating clip is indicated, and within the size range of 2.0 to 3.5mm diameter.

Miriam C. Provost

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

510(k) Number K032238

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)