K070836

15. 510(k) Summary

Summary of Safety and Effectiveness for the ExiClip™ EXCS-M

Date Prepared March 21, 2007

Sponsor

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Common/Usual Name

Device, Percutaneous Biopsy; Clip Applier; Removable Skin Clip

Proprietary Names

ExiClip™ EXCS-M

Classification Information

Classification Name(s):	Device, Percutaneous Biopsy Applier, Surgical Clip Removable Skin Clip
Medical Specialty:	General & Plastic Surgery
Device Class:	I (each of three)
Classification Panel:	General & Plastic Surgery Device Panel
Product Codes:	MJG – Device, Percutaneous Biopsy GDO – Applier, Surgical Clip FZQ – Removable Skin Clip

K070936

Identification of a Legally Marketed Predicate Device

Trade/Device Name:	Shoney Scientific Disposable Punch Biopsy
510(k) Premarket Notification number:	NONE – Class I; 510(k) exempt
FDA Product Code:	MJG – Device, Percutaneous Biopsy
Trade/Device Name:	AutoClip® Applier; AutoClip® Wound Clip (Device: Skin Clip w/ Applicator
510(k) Premarket Notification number:	NONE – Class I; 510(k) exempt
FDA Product Code:	GDO – Applier, Surgical Clip FZQ – Removable Skin Clip

General Description

The ExiClip™ EXCS-M skin biopsy with wound closure device is a single use, disposable device consisting of a removable skin clip, a blade, and a manual delivery system. The device is to be provided sterile. The skin clip is non-absorbable. The skin clip provides wound closure and must be removed after the wound has healed.

Indications for Use

The ExiClip™ EXCS-M is intended to provide a biopsy specimen and/or without biopsy under clinical discretion, remove skin lesions less than 6mm in diameter where simultaneous wound closure is desired.

Summary of Technological Characteristics

The ExiClip™ EXCS-M device is substantially equivalent to the Shoney Scientific punch biopsy in that both devices provide a tissue sample suitable for pathology analysis or remove skin lesions. Both devices are manually powered. Both devices utilize stainless steel blades. Both devices are provided sterile. Both devices have the same intended use – removal of skin lesions and/or provide a tissue sample for pathological analysis.

The ExiClip™ EXCS-M device is substantially equivalent to the AutoClip® Wound Clip with Applier Device (Skin Clip) in that both devices deploy a skin clip for wound closure by activation by plastic deformation of the stainless steel clips via the use of an applier. Both clip appliers have the same intended use which is to apply a surgical clip for wound closure.

The ExiClip™ EXCS-M skin clip has been found to have a comparable retention force to the AutoClip® Wound Clip. Both devices utilize a clip made of stainless steel. Both devices are manually powered. Both devices have the same intended use which is a non-absorbable skin clip for wound closure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cleve X, Incorporated
% Orasi Consulting, LLC
Ms. Lena Sattler
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Loveland, Ohio 45140

APR 20 2007

Re: K070836
Trade/Device Name: ExiClip™ EXCS-M
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: I
Product Code: MJG, GDO, FZQ
Dated: March 22, 2007
Received: March 27, 2007

Dear Ms. Sattler:

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 (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

7. Indications for Use Statement

510(k) Number (if known): K070836

Device Name: ExiClip™ EXCS-M

Indications for Use:
The ExiClip™ EXCS-M is intended to provide a biopsy specimen and/or without biopsy under clinical discretion, remove skin lesions less than 6mm in diameter where simultaneous wound closure is desired.

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

510(k) Number K070136

Prescription Use X
(Per 21 CFR 801 Subpart D)

~~Over-The-Counter Use~~
(Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)