K973313

DEC - 1 1997

510(K) SUMMARY

1. SUBMITTER:

Innovasive Devices, Inc.
734 Forest St.
Marlborough, MA 01752
Telephone: 508-460-8229

Contact: Eric Bannon, Vice President of Quality Assurance and Regulatory Affairs
Date Prepared: August 26, 1996

2. DEVICE:

Trade Name: Innovasive Devices Y-Knot Suture Clip
Classification Name: Implantable Clip
The Product Code is 79 FZP

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for the Innovasive Devices Y-Knot Suture Clip was Ethibond Extra polyester suture produced by Ethicon, Inc., Somerville, N.J.

4. DEVICE DESCRIPTIONS:

The device consists of two distinct assemblies, both of which are required to properly deploy and use the device. These assemblies are the Y-Knot assembly and the handle.

Y-Knot assembly: The shaft portion of the assembly consists of the connector, outer tube, pull rod, shaft tube end, adapter, spring pin and dowel pin. These components are used to support the implant portion of the device and aid in the deployment of the Y-Knot when ready for use. The materials for each of these components are listed on each drawing. The shaft assembly is also fitted with two threaders. This allows the Y-Knot to be threaded with the suture when ready for use. The threaders pass through the inner member of the Y-Knot. When suture is passed through the loop of the threader, the threader is withdrawn. This results in the suture passing through and exiting the inner member. The threader is then discarded.

The implant portion consists of two components, the Y-Knot inner member and the sleeve. The inner member is molded of acetal. The sleeve portion of the device consists of machined acetal.

Handle: The handle will be offered as a reusable component. The handle is a device intended to be connected to the Y-Knot assembly connector and is used to deploy the device. The handle will be offered in two versions. One will be a limited reusable plastic handle constructed of Radel polysulfone material and a stainless steel locking mechanism. A second version, will be an all stainless steel reusable handle for long term reuse.

5. INTENDED USE:

The Intended Use for the Innovasive Y-Knot Suture Clip is for use in general soft tissue approximation and /or ligation.

6. COMPARISON OF CHARACTERISTICS:

The Y-Knot suture clip consists of acetal plastic compared to the polyester material of the Ethicon Ethibond Suture.

The Y-Knot uses a mechanical means through the use of mating parts to secure two ends of a suture. This fixation essentially replaces the knot component of the suture. Suture utilizes a knot as the primary fixation method.

The indications for use for both products are identical.

7. PERFORMANCE DATA:

The following performance data was provided in support of the substantial equivalence determination:

1. Static Strength: The strength of Y-Knot suture fixation with #1 and #2 polyester suture was compared to the same suture utilizing knots and were found to be equivalent.
2. Fatigue Strength: The strength of the Y-Knot compared to the suture with knots was tested at 80% and 60% loads to compare their fatigue characteristics. They were found to be equivalent.

sleeve component at the distal portion of the Y-Knot to move towards, and make contact with, the inner member to which the suture has been passed. As the sleeve mates with the inner member, the suture is captured between the two components. The sleeve then locks onto the locking ring of the inner member. This action of the sleeve mating with the inner member results in the suture not only being secured, but tightened as well. The tightening is due to the suture being drawn up slightly as the sleeve and inner member components mate. As the stroke of the trigger is completed, the inner member pull through component is sheared just above the mating location of the device. The device is now completely deployed resulting in both ends of the suture strand being secured with the Y-Knot Suture Clip. The remaining portion of the device not affixed to the suture is now discarded.

VIII. PACKAGING

The Y-Knot will be packaged in a double protective sterile barrier configuration. The blister will consist of a formed PETG blister or similar material. The lid sealed to the blister will consist of Tyvek 1073B. This package will then be sealed in a chevron pouch. The pouch will consist of mylar laminated to 1073B Tyvek. The blister as well as the pouch will be labeled with the information contained in the labeling section of this submission.

Drawings of the proposed packaging configuration are found in Attachment 7.

IX. STERILIZATION

The method of sterilization for the proposed Y-Knot Suture Clip will be either Ethylene Oxide gas or Gamma Radiation. Each method is summarized below:

A: Ethylene Oxide Gas: The sterility assurance level for this method will 10^{-6}. The sterilization will be completed by a contract facility. The process will be validated per ANSI/AAMI/ISO 11135 - 1994 Half Cycle Method. The ETO residual levels will be 250, 250 and 5000 ppm for Ethylene Oxide, Ethylene Chlorhydrin and Ethylene Gycol, respectively. The Suture Fastener will continue to be labeled as non-pyrogenic. The LAL method will be used.

B: Gamma Radiation: The sterility assurance level for this method will be 10^{-6}. The sterilization will be completed by a contract facility. The process will be validated per ANSI/AAMI/ISO 11137. The minimum acceptable dose for dosimetric release will be 2.5 Mrad, the maximum dose will be 5.0 Mrad. The Suture Fastener will continue to be labeled as non-pyrogenic. The LAL method will be used.

X. LABELING

The Instructions For Use and proposed labeling for the fastener are found in Attachment 8. The labels for the individual sterile fasteners are included as well. These labels are

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Eric Bannon
Vice President of Regulatory Affairs and Quality Assurance
Innovasive® Devices
734 Forest Street
Marlborough, Massachusetts 01752

DEC - 1 1997

Re: K973313
Trade Name: Innovasive Devices Y-Knot Suture Clip
Regulatory Class: II
Product Code: KOG
Dated: September 2, 1997
Received: September 3, 1997

Dear Mr. Bannon:

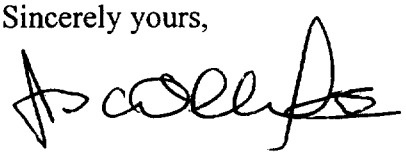
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

The Intended Use for the Innovasive Y-Knot Suture Clip is for use in general soft tissue approximation and /or ligation with #1 and #2 braided polyester suture.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973313