

## Section 7- 510k Summary of Safety and Effectiveness

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**7.1 Statement** This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

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**7.2 Submitter** Smith and Nephew, Inc.  
Endoscopy Division  
130 Forbes Boulevard  
Mansfield, Ma. 02048

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**7.3 Company Contact** Amy Walters  
Clinical/ Regulatory Manager  
(508) 261-3776

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**7.4 Device Name** **Proprietary Name:** Smith & Nephew Suture Collet

**Common Name:**

- Suture Retention Device,
- Endoscopic Accessory,
- Laparoscopic Accessory

**Classification Name:**

- Suture Retention Device (79 KGS)
- Endoscopic accessories (78 GCJ)
- Laparoscopic accessories (85 HET)

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**7.5 Predicate Legally Marketed Devices**

- Suture Lock
- Smith & Nephew and Acufex MIS Instruments

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**7.6 Device Description** The Smith & Nephew Suture Collet System comprises three main components:

- the suture collet implant (ring and pin),
- the disposable cartridge assembly with threader, and
- the reusable delivery instrument.

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**Intended Use** The Smith & Nephew Suture Collet is intended for use in the management of soft vessel ligation and/or fixation of soft tissue structures during open and endoscopic procedures.

**7.8 Device Indications** The Smith & Nephew MIS Instruments are indicated for use in endoscopic procedures, including thoracoscopic surgery and laparoscopic procedures.

**7.9 Substantial Equivalence** The Smith & Nephew Suture Collet is substantially equivalent to the Suture Lock, and silk 2-0 suture. Comparative strength testing demonstrates the equivalence of the Suture Lock to the predicate devices.

The table below summarizes the similarities of the two devices. The similarities in design, materials, intended use, and indications for use between the Smith & Nephew Suture Collet and the predicate devices support the claim of substantial equivalence.

	<b>Suture Collet</b>	<b>Suture Lock</b>
<b><i>Implant:</i></b>		
<b>Product Labeling</b>	Sterile: Single Use Only	Sterile: Single Use Only
<b>Materials</b>	Implant grade polyacetal	Implant grade polyacetal
<b>Indications</b>	Open and Endoscopic/Laparoscopic/Thoracoscopic Surgical Procedures	Open and Arthroscopic Surgical Procedures
<b>Intended Use</b>	Management of Soft Tissue	Management of Soft Tissue
<b>Sterilization Method</b>	Ethylene Oxide	Ethylene Oxide
<b><i>Delivery Instrument</i></b>		
<b>Materials</b>	Aluminum and Stainless Steel	Stainless Steel
<b>Sterilization Method</b>	Supplied non-sterile: must be sterilized prior to use via steam autoclave or ethylene oxide	Supplied non-sterile: must be sterilized prior to use via steam autoclave or ethylene oxide

Applicant *Sperry Walters*

Date 5/23/97



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 6 1997

Ms. Amy L. Walters  
Clinical/Regulatory Manager  
Smith & Nephew, Inc., Endoscopy Division  
130 Forbes Boulevard  
Mansfield, Massachusetts 02048

Re: K971939  
Trade Name: Smith & Nephew Suture Collet and Delivery Instrument  
Regulatory Class: II  
Product Code: KOG  
Dated: May 23, 1997  
Received: May 27, 1997

Dear Ms. Walters:

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.

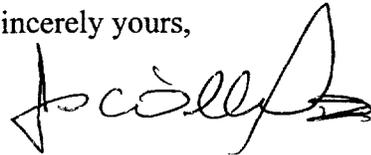
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,



f 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

510 (k) Number (If Known): K971939

Device Name: Smith & Nephew Suture Collet

Indications for Use: The Smith & Nephew Suture Collet is indicated for use in the management of soft vessel ligation and / or fixation of soft tissue structures during open and endoscopic procedures, including thoracoscopic surgery, laparoscopic procedures, and general surgery. The device is not indicated for use in contraceptive tubal ligation.

Intended Use: The Smith & Nephew Suture Collet is intended for use in place of USP size 2-0 knotted silk suture in the management of soft vessel ligation and / or fixation of soft tissue structures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

or Over-The-Counter Use \_\_\_\_\_