K073182

510(k) Summary

Submitted By:

GYN Disposables, Inc.
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NOV 2 8 2007

Contact: James K. Patterson, MD, MBA

Device Classification Name: Tenaculum, Uterine

Device Name: GYN Disposables, Inc. Tenaculum 356T

Classification: 884.4530 Obstetric-gynecologic specialized manual instrument.... (15) A Uterine tenaculum is a hooklike instrument used to seize and hold the cervix or fundus.

Device Class: Class II

Classification Panel: Ob/Gyn Device Panel

Classification Product Code: HDC

Establishment Registration Number: 3006365741

Indication for Use: To snare, grasp, hold and manipulate cervical and intravaginal tissue.

Device Description: GYN Disposables Tenaculum 356T is made of glass reinforced polycarbonate. The GYN Disposable Tenaculum is supplied in a Tyvek pouch and has been sterilized by gamma radiation.

Substantial Equivalence: Atraumatic Tenacula (K930037) and Gynex Iris Hook, Gynex Angle Hook, Gynex Emmett Tenaculum (K980247) are predicate devices.

	GYN Disposables Tenaculum 356T	**Thomasville Medical** Atraumatic Tenaculum	**Gynex Corp** Iris Hook Angle Hook Emmett Tenaculum
510(K) Number	N/A	K930037	K980247
Product Code	HDC	HDC	HDC
Indications for use	Snare, grasp, hold and manipulate cervical and intravaginal tissue	Snare, grasp, hold and manipulate cervical and intravaginal tissue	Snare, grasp, hold and manipulate cervical and intravaginal tissue
Design	Two Tips grasp cervical and intravaginal tissue Handle with two finger holes Ratcheting lock	Two Tips grasp cervical and intravaginal tissue Handle with two finger holes Ratcheting lock	Single tip grasp cervical and intravaginal tissue Single Rod
Material	Glass Reinforced Polycarbonate	302 Stainless Steel	302 Stainless Steel
Sterilization	Purchased Sterile (gamma)	Clean only	Clean only
Single use	Yes	No	No

Material Specifications: GYN Disposables Tenaculum 356T is made with glass reinforced polycarbonate. The advanced composite design can easily withstand forces during normal use as evidenced by performance testing.. In these reports non sterile, gamma sterilized non-aged, and gamma sterilized aged product were tested in four ways to determine strength and weakness in their construction. The first report determined the flexibility and the strength of the arms, the second determined the strength of the tips, and the third report determined the strength of the rack and the force needed to lock the instrument during use. The final report determined the strength of the hinge pin. All test reports showed that the instrument met the minimum acceptance criteria. These tests proved that the material does not degrade because of gamma sterilization and extended shelf life. Another test was done to determine the maximum perceived force during normal use by a physician using a stainless steel tenaculum.

Biocompatibility: The material used by GYN Disposbables, Inc. to make the subject device is a glass-reinforced polycarbonate. This material is made into an OB/GYN instrument called a Tenaculum and is gamma sterilized. The material used is classified by the Rubber And Plastic Research Association (RAPRA) as 43C12 for polycarbonate and 6272 as glass-reinforced. Even though this material or its components have been used in other medical applications and these instruments are only used once and only briefly contacts the patient, GYN Disposables has carried out seven biocompatibility tests on the as-molded, as-sterilized finished instrument.

The first test was an in vitro cytotoxicity test using the following method: the test article was put into the extraction media for not less than 24 hours. The media was incubated for 48 hours and examined for biological activity. Relative to positive and negative controls, the test article did not induce cytotoxicity.

The second test was a similar test except that the extraction was intravenously injected into rabbits. The temperatures of the rabbits were measured for up to 3 hours. This test, called a pyrogen test, in essence is a sensitization and irritation indicator for use of the instrument. These tests found that the as-made instrument did not cause any increase in temperature.

The third test was a hemolysis test. Extracts from the instrument were again made and combined with fresh, whole, rabbit blood using a process that takes approximately 2 hours. The average % hemolysis was determined to be 0.0%, meaning that the extract did not cause damage to blood cells.

In addition to these three tests, four in vivo tests of toxicity were also performed—dermal sensitization in a guinea pig, systemic toxicity in a mouse, and two types of irritation testing (one intracutaneous [between the layers of the skin] and one vaginal) both in rabbits. In all four tests the GYN material passed. Duration of contact of tissue for cytotoxicity, and systemic toxicity was 24, 48, and 72 hours. Contact for Intercutaneous irritation test was 72 hours, vaginal irritation 24 hours for five consecutive days, and systemic toxicity for 1, 1.5, 2, 2.5, and 3 hours.

These seven tests meet and exceed the criteria established in Table 1 in the FDA's 510(k) Memorandum #G95 (dated May 1, 1995) as follows. The disposable Tenaculum instrument has minimal contact duration with the patient and therefore meets Category A (<24hours). It also can worse case be considered an "External Communicating Device" since it is used in the cervix and it also worse case can be considered a "Blood Path, Indirect" product since the cervix is often a bloody field during OB/GYN surgery. According to Table 1, these criteria require cytotoxicity, sensitization, irritation, system toxicity (acute), and hemocompatibility testing. The testing provided are sufficient to assure the passage of the toxicology testing for this device for the brief and one-time intended use. These tests confirm that the manufacturing and sterilization procedures used by GYN do not affect the underlying biocompatibility of the material used.

Sterilization: Product will be sold sterile using gamma radiation. Sterilization validation was performed by Steris in conjunction with Nelson Laboratories. This report follows the ANSI/AAMI/ISO 1137-2:2006 guidelines to perform product qualification for irradiation sterilization of a health care product. Initial verification dosing, bioburden, bacteriostasis/fungistis, and sterility testing were done and acceptance criteria were met. Accelerated aging validation for one year shelf life has been performed by Ethox using sterilized samples. The product packaging met the requirements of the burst test at the non-aged and 1 yr accelerated aged time point. Product packaging met the requirements of the dye penetration test both non–aged and 1 yr aged.

Packaging: Tyvek

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2007

GYN Disposables, Inc.
c/o Mr. Robert Mosenkis
President
CITECH
Medical Device Testing and Consulting
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

Re: K073182
Trade/Device Name: GYN Disposables Tenaculum 356T
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HDC
Dated: November 12, 2007
Received: November 13, 2007

Dear Mr. Mosenkis:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073182

Device Name: GYN Disposables Tenaculum 356T

Indications For Use: Snare, grasp, hold and manipulate cervical and intravaginal tissue.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K073182