MAR 11 2002

2. 510(k) SUMMARY of Safety and Effectiveness

GIMMI GmbH

As required by Section 807.92(c)

2.1 Submitter: [807.92 (a)(1)]

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Germany

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e-mail info@gimmi.de

2.2 Contact Person: [807.92 (a)(1)]

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The Netherlands

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2.3 Date Summary Prepared: [807.92 (a)(1)]

November 30, 2001

2.4 Device Names: [807.92 (a)(2)]

Proprietary GIMMI *ALPHA* Hysteroscopes & Accessories

Common Endoscopic Instruments & Accessories

Classification Names	Product Codes	CFR Reg'n
Cannula & Trocar, Suprapubic, Non-Disposable	78 FBM	876.5090
Tenaculum, Uterine	85 HDC	884.4530
Laparoscope, Gynecologic (and Accessories)	85 HET	884.1720
Screw, Fibroid, Gynecological	85 HHO	884.4530
Hysteroscope & Accessories	85 HIH	884.1690

Instrument, Manual, Specialized (Obstetric-Gynecologic)	85 KNA	884.4530
Endoscope & Accessories	78 KOG	876.1500

2.5 Reason for Submission:

New Devices

2.6 Predicate Devices: [807.92 (a)(3)]

Predicate devices are produced by

Günter Bissinger Medizintechnik
Comeg Endoscopy
Dufner Instrumente GmbH
Henke-Sass Wolf, GmbH
Optus, Inc.
Pilling Weck Group
Wolf
Karl Storz Endoscopy
and a wide range of other manufacturers

2.7 Device Description: [807.92(a)(4)+(6)]

GIMMI *ALPHA* Hysteroscopes are comprised of rigid, panoramic telescopes using rod lens technology. The body contact portions are composed of surgical grade stainless steel, which is commonly used in medical devices for a wide range of applications and has a long history of biocompatibility for human use.

Laparoscopic and obstetric-gynecologic accessories are composed of reusable handle and shaft assemblies and removable, reusable tip assemblies. Some specialized instruments, such as the gynecologic fibroid screw and uterine tenaculum are one-piece.

The instruments are designed and manufactured specifically for the purpose of manipulating soft tissue structures (grasping, cutting, dissecting, coagulating and suturing).

2.8 Intended Use: [807.92 (a)(5)]

GIMMI *ALPHA* Hysteroscopes and Accessories are intended to be used by qualified physicians to provide access, illumination and visualization of the cervical canal and the uterine cavity by a telescopic system introduced into the uterus through the cervix. These generic devices are used to perform diagnostic and surgical procedures.

2.9 Industry Standards/Performance Data: [807.92 (d)]
GIMMI certifies compliance with relevant ISO/EN/ASTM/

AAMI/ANSI/IEC and other device-related standards that apply to the manufacture, packaging, labeling, and reprocessing of subject devices including the validation of these processes.

2.10 Summary of Testing
All materials used in the composition of GIMMI *ALPHA* Hysteroscopes and Accessories were subjected to performance and physical tests to evaluate safety, effectiveness, and reliability of the devices. All results were in conformance with the cited harmonized device standards.

2.11 Information Bearing on the Safety and Effectiveness:
[807.92 (b)(3)]
The GIMMI *ALPHA* Hysteroscopes & Accessories have the same intended use as predicate devices. They are made of the same material and produced to the same international and FDA-recognized standards. Slight modifications in design do not adversely affect the safety and effectiveness of these devices.

In summary, the
- intended use
- performance attributes
- materials and
- basic design

are identical and/or substantially equivalent to SE devices.

The results of design validation raise no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2002

GIMMI GmbH
% Mr. Dagmar S. Mäser
Business Support International
Amstel 320-I, 1017 AP Amsterdam
THE NETHERLANDS

Re: K012869
Trade/Device Name: Gimmi Alpha Hysteroscopes & Accessories
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscopes and accessories
Regulatory Class: II
Product Code: 85 HIH
Dated: December 18, 2001
Received: December 20, 2001

Dear Mr. Mäser:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

510(k) Number K012869

Device Name GIMMI *ALPHA*®
Hysteroscopes & Accessories

INDICATIONS FOR USE

GIMMI ALPHA® Hysteroscopes and Accessories are intended to be used by qualified physicians to provide access, illumination and visualization of the cervical canal and the uterine cavity by a telescopic system introduced into the uterus through the cervix. These generic devices are used to perform diagnostic and surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per CFR 801 109)

(Optional Format 1-2-96)

V

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012869