K970107

## 510(k) SUMMARY

In accordance with the requirements of SMDA 1990 and 21 CFR 807.92 this 510(k) Summary of Safety and Effectiveness is submitted with the Premarket Submission.

NOV 18 1997

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| Company Name: | UROHEALTH Systems, Inc.<br>3050 Redhill Ave.<br>Costa Mesa, CA 92626 |
| Contact Person:<br>Telephone Number: | Ronald Bergeson<br>714.708.7748, ext. 248 |
| Device Name: | Bronchoscope |
| Proprietary Device Name: | Intubation Endoscope and Introducer Sheath |
| Classification Name: | Bronchoscope (flexible or rigid) and accessories |
| Predicate Devices: | SteBar Instr. Corp. Schroeder Oral/Nasal Stylette™<br><br>Vision-Sciences EndoSheath®<br><br>AMERICAN OPTICAL Flexible Brochoscope FBS-1<br><br>Karl Storz Intubation Fiberscope |
| Device Description: | UROHEALTH Intubation Endoscope Introducer Sheath is a device that consists a malleable or nonmalleable introducer sheath that houses a channel for insufflation of oxygen or fluid delivery, a deflecting mechanism for the distal tip, a channel for scope insertion, and a distal window. The reusable fiber optic imaging and illumination system consists of a focusing ocular lens, a distal objective lens, and a connection for a fiber optic light cable. |

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| Intended Use: | The Intubation Endoscope and Introducer Sheath are used in the direct visualization in the trachea and lungs during fiberoptically assisted intubation and airway management. |
| Performance Testing: | The Intubation Endoscope and Introducer Sheath will be tested to ensure integrity of the sterile barrier under normal usage conditions. All bonded joints will tested according to the appropriate ASTM procedure. |
| Biocompatibility: | Biocompatibility testing will be conducted on both component level and finished devices (sterile, if applicable). This testing will include but is not limited to cytotoxicity, sensitization, and irritation. The device is considered body contact surface of mucosal membranes for a limited (less than 24 hours) contact duration. This testing is in accordance with EN 30993 for medical devices. |
| Substantial Equivalence: | Based on the indications for use, technological characteristics, and safety and performance testing to be completed, the UROHEALTH Intubation Endoscope and Introducer Sheath will be shown to be safe and effective for its intended use. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1997

Ronald Bergeson
Corporate Director, Regulatory Affairs
Imagyn (formerly UroHealth)
5 Civic Plaza
Suite 100
Newport, CA 92660

Re: K970107
Intubation Endoscope and Introducer Sheath
Dated: October 7, 1997
Received: October 8, 1997
Regulatory class: II
21 CFR 874.4680/Procode: 77 EOQ

Dear Mr. Bergeson:

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 requirement, 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) 594-4613. 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,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K970107

Device Name: Intubation Endoscope and Introducer Sheath

Indications for Use:

The Intubation Endoscope is used for direct visualization in the trachea and lungs during fiberoptically assisted intubation and airway management.

(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 21 CFR 801.1091

(Optional Format 1-2-96)

David C. Segroves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970107

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