SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name:

Cytyc Surgical Products NovaCyte™ Microendoscope and Accessories

Manufacturer Information:

Cytyc Surgical Products
1047 Elwell Court
Palo Alto, CA 94303

Contact: Jim Talbot Phone: (650) 335-2639 Fax: (650) 335-2638 E-Mail: jim.talbot@cytyc.com

Establishment Registration Number: 3003407659 (copy page 10)

FDA Device Classification:

Standard Product Nomenclature:	Laparoscope, General & Plastic Surgery
Device Description:	Endoscope and Accessories
Medical Specialty:	General & Plastic Surgery
Product Code:	GCJ
Device Class:	II
510(K) Exempt?	No
Regulation Number:	876.1500

Intended Use and Product Description:

The NovaCyte™ Microendoscope will be labeled for the intended use of:

This device is to be used by a physician for viewing an interior cavity of the human body through either a natural opening or incision.

The NovaCyte Micro endoscope is a semi-rigid fiberscope intended for limited reuse (not to exceed 10 procedures) and is provided non-sterile. The NovaCyte Micro endoscope must be sterilized prior to use. Refer to the Handling, Cleaning and Sterilization instructions. The NovaCyte Accessory Pack is comprised of a solid obturator (dilator) and an Introducer (Cannula). It is intended for single use and is provided sterile.

Substantial Equivalence/Predicate Device:

Establishment of equivalence is based on similarities of intended use, design, and materials, physical characteristics and geometry between the Cytyc Surgical NovaCyte Microendoscope and the Acueity Microendoscope (Viaduct) (K011189) and the Davlite Microendoscope (K020310) among other marketed visualization products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2005

Mr. Jim Talbot
Director, Quality and Regulatory Affairs
Cytyc Surgical Products
1047 Elwell Court
Palo Alto, California 94303

Re: K050650
Trade/Device Name: NovaCyte™ Microendoscope and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 25, 2005
Received: April 25, 2005

Dear Mr. Talbot:

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 Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CYTYC

K050650 NovaCyte™ Microendoscope and Accessories

Indications for Use

510(k) Number : K050650

Device Name: **NovaCyte™ Microendoscope and Accessories**

Indications for Use:

This device is to be used by a physician for viewing an interior cavity of the human body through either a natural opening or incision.

Prescription Use: Yes AND/OR Over-the-Counter Use: No
(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 General, Restorative
and Neurological Devices

510(k) Number K050650