

AUG 30 1999

## **510(k) Statement (Section 807.93)**

### **Application: Cystoscopes**

#### **A. Summary of Safety and Effectiveness**

We compared our Cystoscope prototypes in detail to much older equipment, manufactured by R.Wolf and other Manufacturers and we conclude that our Cystoscopes are as safe and effective as all other devices earlier and currently on the market. Our designs, lens-systems, materials, glues and epoxies are commonly used by the endoscope industry.

#### **B. Parts of finding Substantial Equivalence**

We compared our manufacturing drawings with corresponding devices from R.Wolf. We found substantial equivalence in all significant details.

#### **C. Descriptive Information**

We intend to manufacture our Cystoscopes under strict GMP Guidelines: From incoming material registration and testing to detailed manufacturing instructions and device master and history filing including complaint reporting.

#### **D. Performance Testing**

Our Prototypes underwent extensive mechanical and thermic stress testing to assure safe and long term use.

#### **E. Adverse Health Effects**

We are not able to determine any adverse health effects compared to the already marketed devices and can not imagine any possibility of this kind.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 30 1999

Mr. George Abulescu  
President  
Medifix, Inc.  
8727 Narragansett  
Morton Grove, Illinois 60053-0000

Re: K992483  
Medifix Inc. Cystoscopes  
Dated: July 23, 1999.  
Received: July 26, 1999  
Regulatory Class: II  
21 CFR §876.1500/Procode: 78 FAJ

Dear Mr. Abulescu:

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 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). 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.  
Acting 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): K992483 Page 1 of 1  
Device Name: Cystoscope / MEDIFIX Inc.

Indications for Use:

**Operative and Diagnostic Cystoscopy for visual imaging and light transmission.**

(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 801.1091)

OR

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

(Optional Format 1-2-96)

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(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K992483