K072613

510(k) SUMMARY

Prepared: August 28, 2007
Revised January 8, 2008

APR 21 2008

CONTACT INFORMATION:

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DEVICE NAME: ***DirectView*™ Model 10RLL-320 Laparoscope**
***LightGuide* Model 10DLG-320 Disposable 0 Degree**
Angled *LightGuide* Model 10DLG-3215 15 Degree
Angled *LightGuide* Model 10DLG-3222 22 Degree
Angled *LightGuide* Model 10DLG-3230 30 Degree

EQUIVALENCE: Wolf Lumina Model 8934.40

INDICATION FOR USE

UROLOGY
DirectView™ Endoscopes may be used by qualified physicians for imaging of a surgical site for diagnostic and surgical urology procedures.

GENERAL SURGERY
DirectView™ endoscopes may be used for general diagnostic and laparoscopic surgical procedures by a qualified physician for visualization of body cavities, organs, and canals to perform various diagnostic and surgical procedures.

PRODUCT DESCRIPTION:

A laparoscope is a device used for minimally invasive surgery for specific indications of use. The device consists of two separate and distinct optical paths. The illumination usually takes the form of fiber optics connected to a light cable which brings light from an external light source to the instrument.

The second path is an optical telescope that captures an image from inside the body cavity with an optical objective lens system. This image is then transmitted through a series of optical relay lenses and/or rods to convey the image to a eyepiece for viewing by the human eye. Over the years, human viewing using the eyepiece has given way to electronic cameras which projects the image from the telescope on to a video monitor. Recent designs using what is called a chip-on-a-stick technology has replaced the optical relay with an electronic camera embedded in the distal end of the device at the expense of bringing wiring into the body cavity.

The basic optical design as well as physical design of the laparoscope has remained constant with the exception of the reduction of its diameter. The device has remained essentially the same since the original Hopkin's design over forty years ago. Major developments have occurred, however, in the application of solid state camera systems and high definition video monitors creating a revolution in minimally invasive surgery. MITI seeks to make major revisions in the basic design of the device itself to address problems which have

largely been unaddressed for decades. MITI defines functionality of its technology in terms of flexibility, sterility, visibility, interchangeability, availability, safety, and affordability.

Flexibility is a prominent part of the MITI laparoscope design, The modular capability allows it use in a range of different laparoscopic configurations with and without endo couplers (endo couplers are not provided by MITI), direct and indirect camera connections, elimination of 90% of the fiber optics used for illumination, 75% fewer lenses than conventional endoscopes, offer a protective sheath coverage of cameras and endo couplers to extend their operating lives and the elimination of the 90 degree light cable connection to improve ergonomics.

Visibility. By definition, surgery is a bloody process; therefore, devices used in surgery get bloody and often covered in protein as well. Unfortunately, optical lenses, particularly small ones which get covered in blood and protein obscure the image transmission through them destroying image quality and resolution. Today's surgeon finds it necessary in many cases to clean them on internal organs. For example, if during a gall bladder procedure the image becomes obscure; the surgeon will often clean it on the liver. This is not necessarily the most efficient way to clean a lens; it may even be dangerous in spreading infection from one organ to another. It is also unacceptable to clean angular laparoscopes in this manner as it could penetrate the organ. The MITI laparoscope addresses this serious problem by enabling the disposable *LightGuide* to be removed and replaced in a matter of seconds returning the laparoscope image to unobstructed quality.

Sterility. MITI is acutely aware of the problems with nosocomial infections, many of them occurring with improperly sterilized instruments. Also the complexity and cost of cleaning these devices for repeated use also represents a known problem. MITI addresses these problems by developing a single use element that is low in cost and can be disposed of after each medical procedure. The company has developed a telescope system with an image quality that is the equivalent to instruments being sold in the market. It has coupled this optical design, with an illumination system (LightGuide) that is made of high transmission plastic rather than of glass fibers. In addition, the company has integrated a protective shield at the proximal end of the *LightGuide* to encapsulate the eyepiece and camera system to keep the entire unit in a sterile field, essentially creating a new laparoscope for each patient.

Interchangeability. In using the MITI *LightGuide* System with interchangeable viewing angles, the surgeon is able to change from one angle to another with the same optical telescope, camera and video monitor. Changing angles can be accomplished in a matter of seconds by removing one and inserting the other, with all camera and video monitor settings remaining the same. In addition, the angled *LightGuides* have an additional feature that eases the surgeon's workload. Instead of requiring the surgeon to rotate the entire laparoscope, including the light cable and camera system, the MITI system can rotate the image by simply rotating the *LightGuide*, which can be rotated continuously, a full 360 degrees. If the laparoscope becomes obstructed with blood and protein, the MITI system can regain full image quality by simply replacing the *LightGuide*, whether it is a 0 or any other angled one..

Availability. Because the laparoscope internal components are sealed in a sterile environment by the use of the light guide and protective shield, they can be used without re sterilizing. In addition to protecting sensitive devices like cameras and endo coupler, increases there availability as they need not be out of service for sterilization. This is particularly the case with angular units which because of their high cost are less likely to be available.

Safety. Since the advent of RF Scalpels, RF suturing and other electronic devices used during surgery, the stainless steel construction of existing laparoscopes is a potential electrical hazard. The laparoscope housing is connected to an electrical ground with can short circuit other electrical devices during surgery. The MITI light guides are made of non conductive, non moisture absorbing cyclic polyofin. It is not only non conductive to electricity, it does not conduct heat as well.

Afordability. The hospitals, clinics and doctor's office inventory of fixed angled laparoscopes can be significantly reduced as the need to maintain inventory of the numerous angles used by the surgeon can be minimized by the interchangeable system. Furthermore, the sterilization process of the telescope can reduce the chance of infection from improperly sterilized instruments and significantly reduce the time necessary to clean and sterilize the reusable instrument.

Currently laparoscopes have a useful life of approximately 75 to 100 surgeries before they become unusable either from the deterioration caused by sterilization, damage from handling, peeling of optical coatings because of heat and humidity. Once this occurs, laparoscopes are sent out for reprocessing. The FDA has recently ruled that the reprocessing must be accomplished by companies authorized to perform this task. This is a result of edicts in support of preventing infection from unqualified vendors. Because of its efficient optical design with 75% fewer components may make reprocessing obsolete.

Micro Invasive Technology Inc. (MITI) *DirectView*™ Laparoscope is a zero (0) degree, 10 millimeters in diameter and 320 millimeters long with a 70 degree, plus field of view, which is essentially the same as the predicate device, a Wolf *Lumina* model zero degree laparoscope. The *DirectView*™ Laparoscope differs from the Wolf Model in one respect. In place of the fiber optics used by the Wolf Model to illuminate the subject area in the body cavity, MITI uses a plastic rod in place of individual light fibers.

OPTICAL TELESCOPE. The *DirectView*™ and Lumina laparoscopes both have an optical system consisting of an objective lens and a relay lens system to transmit images from within the body cavity to a eyepiece for viewing. Technology developments in solid state cameras has essentially made viewing through an eyepiece obsolete and most laparoscopes are connected to cameras by an optical interface called an endo-coupler. The MITI optical design is a function of modern optical design software development enabling a more efficient system design with fewer lens components. These efficiencies are highlighted in the photographs of a more detailed description in a later section.

The MITI design is modular, in that it can be used in a standard manner with an endo coupler along with the eyepiece, however, further efficiencies can be gained by eliminating the eye piece and connecting the telescope directly to the camera eliminating the need for both the eyepiece and endo-coupler. To achieve this efficiency, the MITI telescope design incorporates a means of adjusting the focus and orientation of the optical image in the body of the telescope. These elements can be removed for purposes of convention, as MITI provides the laparoscope with an eyepiece for those physicians who are more comfortable with the traditional endo-coupler.

ILLUMINATION. The conventional illumination of the internal body cavity is brought about by a bundle of fiber optic light wires which surround the optical telescope. The light wires are condensed into a single interface called a ferrule (there are numerous light cable adaptors used by different manufacturers) which connects to a fiber optic light cable and intern to a light source. The light source is typically 150 to 500 watts of continuous light. Filters are used to remove as much heat (Infrared light) as possible. The *DirectView*™ laparoscope uses a very shallow bend in the fiber optic to convey the illumination light into the body cavity. This makes minimizes light losses as well as reducing thermal effects.

The *DirectView*™ Model 10DLG-320 Disposable *LightGuide* system uses the same fiber optic light wire interface but terminates the interface at an annulus at the proximal end of the telescope. The 10DLG-320 disposable rod consisting of a high transmission plastic carries the light from the annulus into the body cavity to illuminate the surgical site. The plastic rod is terminated by a lens which seals the end of the rod keeping the telescope totally encapsulated to prevent contact with human tissue. At the interface between of the annulus and disposable rod, a protective sheath may be unrolled to keep the telescope, an endo coupler, camera and light and camera cables in a sterile field.

The Models 10DLG-3215, 3222 AND 3230 are disposable angular viewing *LightGuides* which capture images from angles that are not on axis with the optical telescope. These *LightGuides* are interchangeable with the 0 degree *LightGuides* and with each other. The angled *LightGuides* are designed using a high refractive index optical glass and mounted with the prism angle inverted, whereby the flat surface faces the image and the angled prism surface face the objective lens. Drawings showing this configuration are enclosed in this submission. Performance data is also enclosed.

The disposable plastic *LightGuides* are constructed using the same material (Zeonex 790R),for all *LightGuides*. The plastic rod is incorporates a prism at the distal end which seals the end of the rod keeping the telescope encapsulated in a sterile field as with the 0 degree *LightGuides*. The plastic rod is ground and polished at the same angle as the prism viewing angle to illuminate the viewing area in the body cavity.

The packaging and ETO sterilization process is the same for all the angled *LightGuides* as with the 0 Degree *LightGuides*. They are all constructed using the same materials and cements, tested for leakage and packaged in the same sterile packaging.

All *LightGuides* are designed to be opened in the operating room immediately prior to use and to be disposed immediately after the surgical or diagnostic procedure in appropriate medical waste containers. MITI has designed the light guides to shrink in size if re-sterilization is attempted with any process that would increase the temperature of the light guide to over 200 degrees Fahrenheit.

DATA ASSESSMENT. Data reported in another section of the application shows photographs of the ™ and the Lumina under identical test configurations with identical test targets, primarily AF standard resolution targets. The targets were placed at the same distance from the distal end of the laparoscopes and photographed using two different camera systems. One camera used an NTSC format and Sony monitor. The other used a digital camera with VGA high resolution monitor with increased resolution. Photographs show the results of these tests as well as the test configuration. An empirical test of skin tissue is shown in photos 1 & 2 that demonstrate the equivalency results on human tissue.

Conclusions:

The MITI *DirectView™* has a slightly greater field of view than the Wolf Lumina. This is reflected in the slightly larger image of the test targets at the same distance. For purposes of this document, the instruments are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2008

Micro Invasive Technology, Inc.
% Mr. John Bala
President and Regulatory Officer
934 North Main Street
Danielson, Connecticut 06239

Re: K072613
Trade/Device Name: DirectView™ Laparoscope and Disposable LightGuide
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: November 30, 2007
Received: December 17, 2007

Dear Mr. Bala:

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.

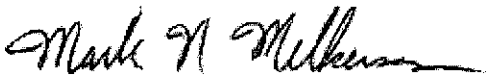
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K072613

Device Name: *DirectView*™ Laparoscope and Disposable LightGuide

Indication For Use:

UROLOGY
DirectView™ Endoscopes may be used by qualified physicians for imaging of a surgical site for diagnostic and surgical urology procedures.

GENERAL SURGERY
DirectView™ endoscopes may be used for general diagnostic and laparoscopic surgical procedures by a qualified physician for visualization of body cavities, organs, and canals to perform various diagnostic and surgical procedures.

Prescription Use __X__ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Neil R P Ogden for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072613