General Robotic Devices, Inc.

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NOV 13 1997

510(K) SUMMARY

K970782

Company:	General Robotic Device, Inc. 2069 Golfside Drive Ypsilanti, Michigan 48197
Contact Person:	Yansong Shan, Ph.D. Phone: 313-572-1102 Fax: 313-572-1132
Date of Summary Preparation	February 28, 1997

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1. DEVICE IDENTIFICATION

Device Name:	Spatial Imaging Sensor for Endoscopy
Trade Name:	Imaging Jet
Proprietary Name:	Imaging Jet
Classification Name:	Endoscope and accessories 21 CFR 876.1500
Classification:	Class II

K970782

2. Predicate Devices

1. X-ray fluoroscopy instrument by Picker International, Inc. (Cleveland, OH)
2. Endoscope and Accessories: Measuring Device by Olympus, Inc.

3. Description of the Device

The Imaging Jet is an endoscopic accessory that provides a spatial view of an endoscope inside a patient. When in use, the sensor catheter is inserted into the biopsy channel of an endoscope inside a patient. The sensor catheter measures the shape of a scope and sends sensory signals to a computer for calculating and displaying the image on the computer screen.

A complete Imaging Jet system consists of the following major components as shown in: (1). a computer which governs the operation of the whole system, calculates the scope spatial image and displays the image; (2). a signal processing unit which acquires and processes the sensory signals and supplies them to the computer for image calculation; (3). a sensor catheter which is a long flexible rod with sensors embedded inside in its head portion; (4). a sensor catheter transport unit which is used to insert and withdraw sensor catheter into and from the biopsy channel of a scope; and (5). a mobile stand for transporting the whole system.

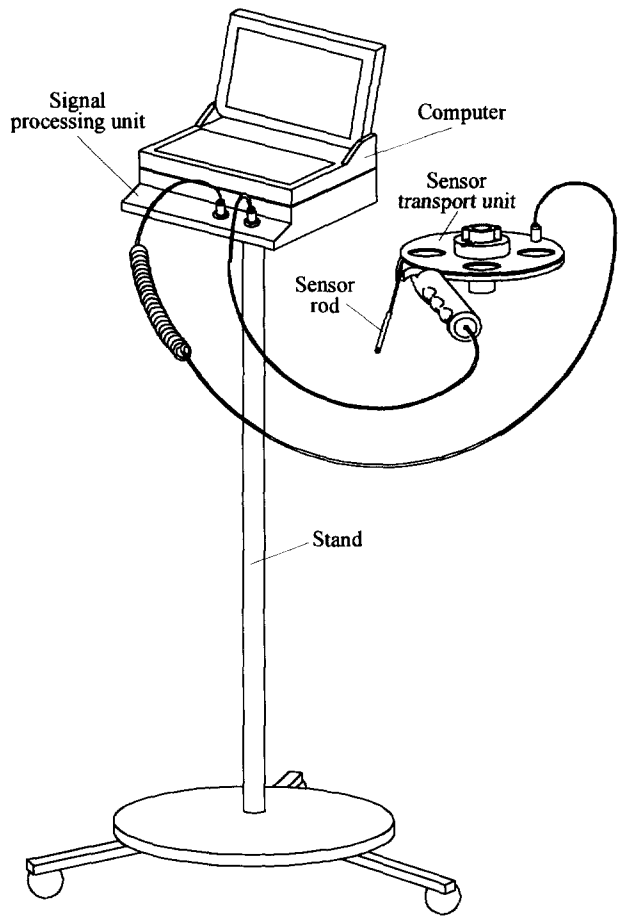

Figure 3-1. System overview

The signal processing unit houses all the electronics and power supplies to the system. The unit measures *400 mm x 300 mm x 100 mm* (*L×W×H*) and weighs about *3 kg*. The signal processing unit is shown in Figure 3-2.

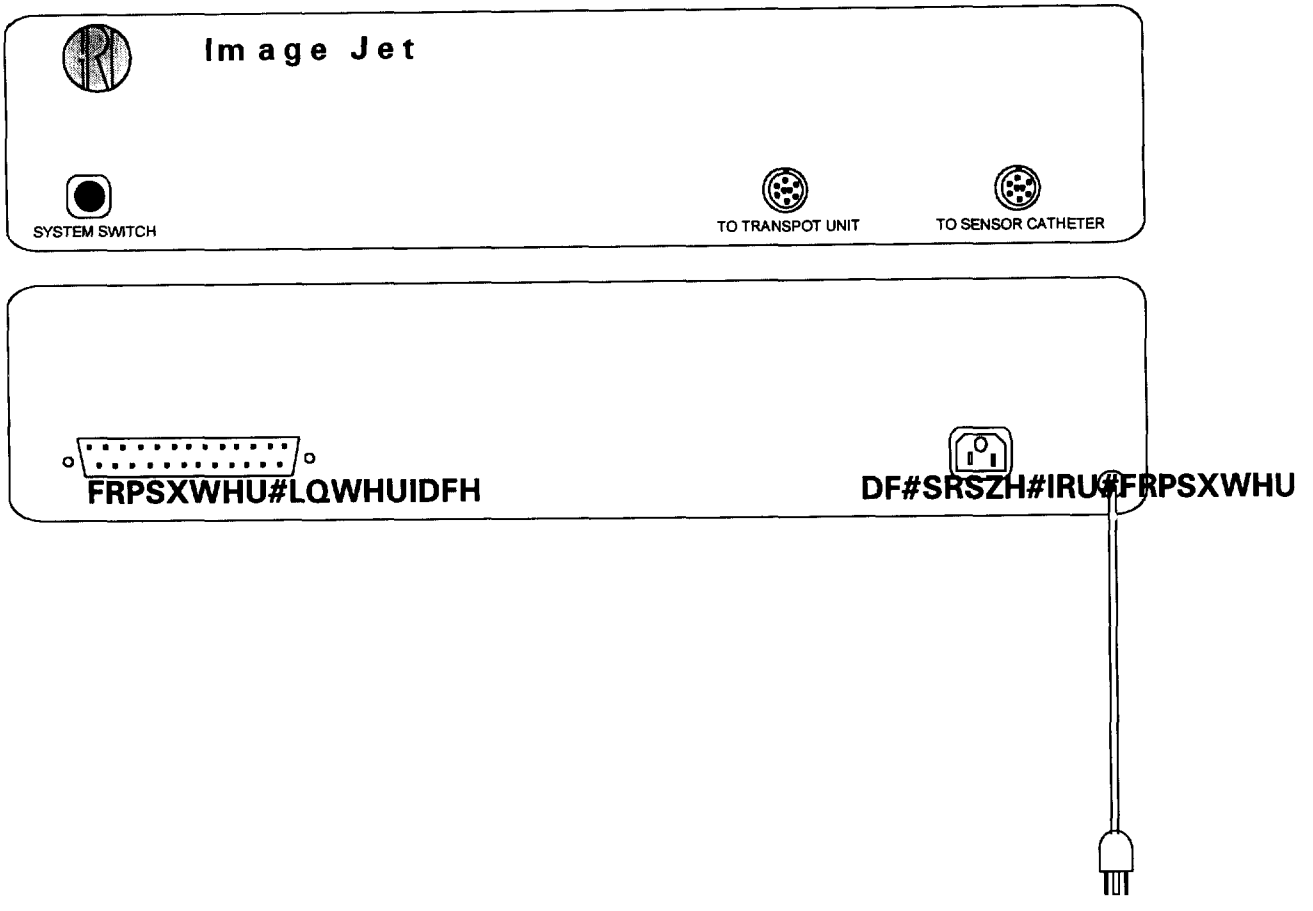

Figure 3-2. Signal processing unit

The sensor catheter consists of two segments. At the tip of the catheter, there is a sensor head segment where sensors are embedded. The rest is used to provide the necessary length. The sensor catheter is shown in Figure 3-3. During application, only the sensor head and part of the insertion tube are inside the endoscope, the rest of the catheter including the rear part of the tube and sensor catheter connector are outside the scope (They remained inside the transport unit).

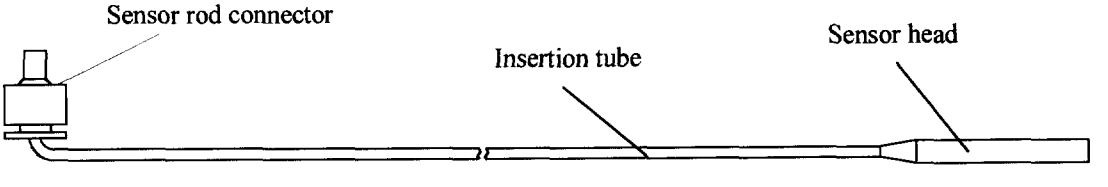

Figure 3-3. The sensor catheter

The sensor catheter transport unit is used to automatically insert and withdraw sensor catheter into and from the biopsy channel of a colonoscope. This will reduce the work load on the physician, meanwhile maintains a smooth sensor motion that will result in good quality of sensor signals. The sensor catheter should be loaded into the transport unit prior to an operation by doctor's assistant. This unit also generates feedback to the control unit so that the actual insertion motion of the catheter can be monitored and controlled. The transport unit is shown in Figure 3-4.

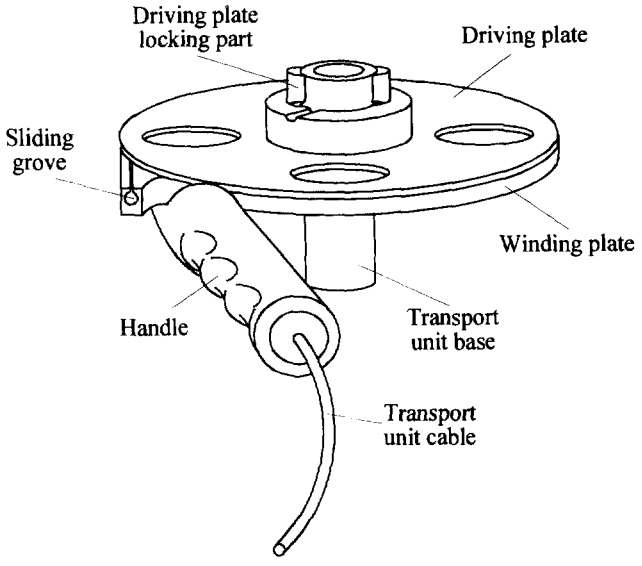

Figure 3-4. The sensor catheter transport unit

The sensor catheter transport unit delivers the sensor catheter through the biopsy channel of an endoscope. During insertion, the catheter detects curvature of the path of the biopsy channel and sends electrical signals to the signal processing unit. The computer interfaces with the signal processing unit and calculates the image of the endoscope. After the computer calculates the image of the endoscope, it displays the image onto the computer screen in a three dimensional manner.

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4. Statement of Intended Uses

The Imaging Jet System provides physicians with a three dimensional image of an endoscope inside a patient.

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5. Substantial Equivalence Comparison

Table 5-1. Substantial Equivalence Comparison Table

	Imaging Jet	Predicate device Fluoroscopy	Predicate device Measuring Device
Intended use	determine (1) overall image of a scope, (2) existence and direction of loops, (3) number of loops, and (4) location of lesion.	determine (1) overall image of a scope, (2) existence and direction of loops, (3) number of loops, and (4) location of lesion.	Measure the size of the polyp.
Technology characteristics	This device uses sensors to measure the curvature of a scope along the insertion length while the catheter traveling through the endoscope biopsy channel. The 3D position estimation is obtained from the sensor signals of the catheter. Then the 3D scope image is displayed on a computer screen using computer graphics techniques.	The x-ray cameras are built based on the penetration of the x-ray into a patient. The scope inside the patient blocks the x-rays that directly fall to the scope. Therefore, there is a difference on radiation intensity on the receiver. The x-ray image can be formed by displaying the image on to a screen. The screen can directly show the image of the scope inside the patient.	This device allows doctors to measure the size of a polyp by compare it with the measuring marks on the device.
Method of application	The sensor catheter is inserted through the biopsy channel of the endoscope in concern and reaches the distal end of the endoscope.	An x-ray camera is outside the patient.	The measuring device is inserted through the biopsy channel of the endoscope in concern and reaches the distal end of the endoscope.
Target population	Patients with "difficult" colon while needing colonoscopy and most patients who need small bowel endoscopy.	Patients with "difficult" colon while needing colonoscopy and most patients who need small bowel endoscopy.	Patients with polyps and the size of the polyps is in concern.
Biocompatibility	All exterior materials are biocompatible.	Not applicable.	All exterior materials are biocompatible.
Performance	(1) The shape measurement accuracy of this device is ±4%. This accuracy is sufficient for its intended use.	(1) The accuracy of position estimation is at best 10 mm, but in fact much worse. (2) Multiple pictures need to be taken to pro-	Provide quantitative measure of the size of a polyp.

	(2) Provide a three-dimensional image in one operation. (3) User can manipulate the image to facilitate understanding.	vide three dimensional information. (3) In general, while using fluoroscopy to determine the location of an endoscope, a physician uses a single two-dimensional image and attempts to extrapolate a three dimensional image. The error in this extrapolation is great, several centimeters at least. This error is increased by changing rate of magnification as the x-ray beam travels from the x-ray emitter to the x-ray receiver.	
Radiation safety	No radiation hazard.	Radiation health hazard to patients, operators, and other personnel in the room. Possible damage to the scope overtime.	No radiation hazard.
Sterility and cleaning	Cleaning and disinfection are needed after each use.	Cleaning and sterilization are not needed.	Cleaning and disinfection are needed after each use.
Energy used	Electricity	Electricity	No energy source needed
Where used	Any doctor's office	Hospital or major clinics	Any doctor's office
Physical appearance	The appearance of the sensor catheter can be characterized as a "rod".	An x-ray emitter and a receiver.	The appearance of same this device can be characterized as a "rod".

In summary, the Imaging Jet has the same intended use as that of the x-ray fluoroscopy instrument for endoscopy procedures. The effectiveness of this device is established through thorough mathematical analysis. The safety is established through material selection, system design, manufacturing quality control, and mathematical proof. This system provides similar information as an x-ray fluoroscopy instrument and offers several advantages over an x-ray fluoroscopy instrument: (1) There is no radiation hazard to patients and operators, (2) Low cost in both facility and usage, (3) Easy to use, no need to transport patients back and forth between x-ray unit and endoscopy unit, (4) It provides a full three-dimensional image, and (5) Users can manipulate the image to facilitate understanding. As a result of the above analysis, we consider the Imaging Jet is substan-

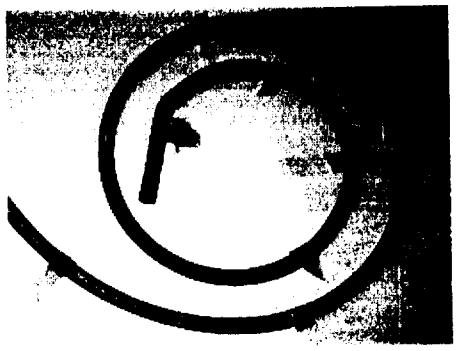
tially equivalent to the x-ray fluoroscopy instrument for its intended use and the Image Jet is at least as safe and effective as the x-ray fluoroscopy.

The common technical characteristics of both Imaging Jet device and the Endoscope Measuring Device by Olympus can be summarized as: (1) When in use, the catheters of both the Endoscope Measuring Device by Olympus and the Imaging Jet are inserted into the biopsy channel of an endoscope. (2) Both devices contain no invasive tools, e.g., tools for biopsy forceps, at their distal ends. Their physical appearances can both be characterized as "rod". (3) During use, both devices may contact the interior tissue of a patient. The safety of both devices is ensured through the biocompatibility of the materials selected to construct the devices.

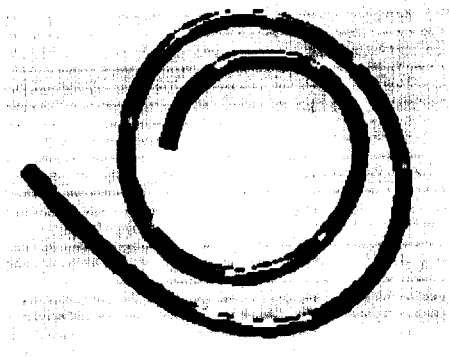
Therefore it is concluded that the Imaging Jet device achieves the same intended use as the predicate device (x-ray fluoroscopy instrument by Picker) and it is as safe and effective as the predicate devices (x-ray fluoroscopy instrument by Picker and Endoscope and Accessories: Measuring Device by Olympus, Inc.).

6. Performance

Laboratory tests were conducted to test the performance of the Imaging Jet system in terms of the overall image calculation capability, we used a colonoscope to form different shapes. Then we used the Imaging Jet system to measure these shapes. The following figures illustrate the comparison between the actual scope images and the measured images using Imaging Jet.

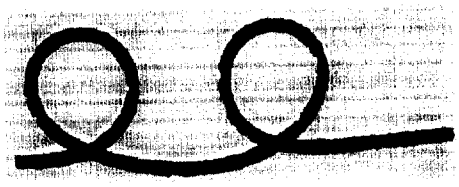


(a1) Actual scope image



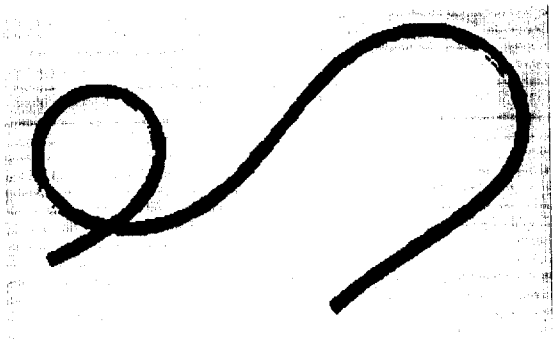
(a2) Measured image using Imaging Jet

(b1) Actual scope image



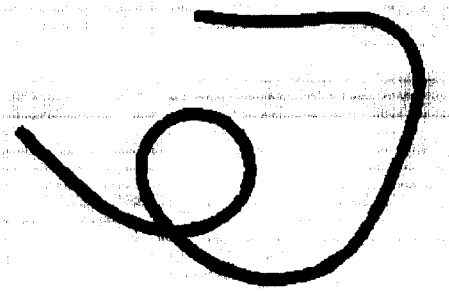
(b2) Measured image using Imaging Jet

(c1) Actual scope image



(c2) Measured image using Imaging Jet

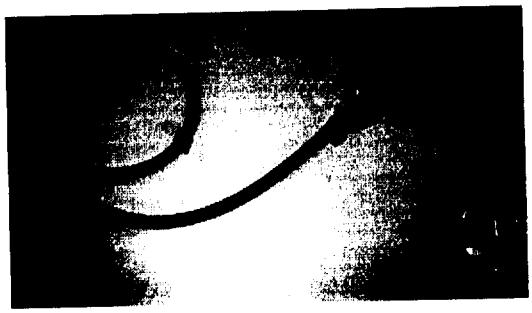
(d1) Actual scope image



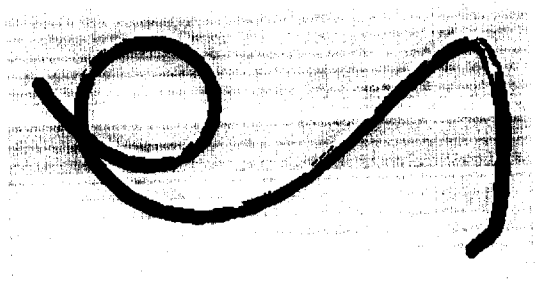
(d2) Measured image using Imaging Jet

(e1) Actual scope image

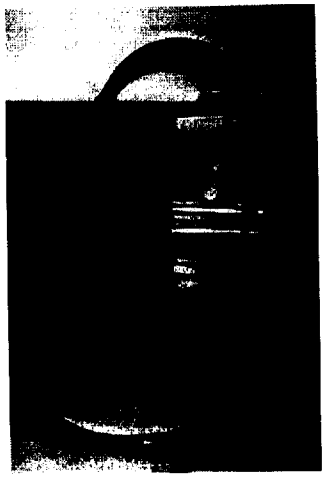
(e2) Measured image using Imaging Jet



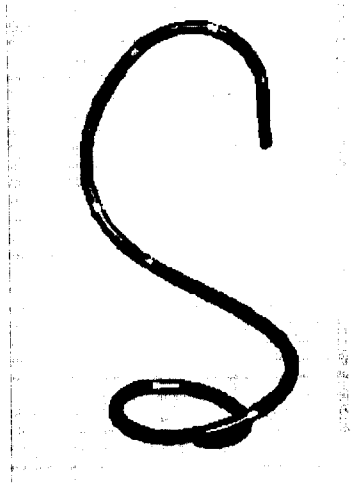
(f1) Top view of actual scope image



(f2) Top view of measured image using Imaging Jet



. (f3) Side view of actual scope image



(f4) Side view of measured image using Imaging Jet

Figure 6-1. Image comparison

From the above figures, we conclude that the Imaging Jet system is capable of generating images with sufficient accuracy for its intended use.

7. Conclusions

In summary, the Imaging Jet has the same intended use as that of the x-ray fluoroscopy instrument for endoscopy procedures. The effectiveness of this device is established through thorough mathematical analysis and laboratory tests. The safety is established through material selection, system design, manufacturing quality control, and mathematical proof.

Therefore it is concluded that the Imaging Jet device achieves the same intended use as the predicate device (x-ray fluoroscopy instrument by Picker) and it is as safe and effective as the predicate devices (x-ray fluoroscopy instrument by Picker and Endoscope and Accessories: Measuring Device by Olympus, Inc.).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 1997

Yansong Shan, Ph.D.
President
General Robotic Devices, Inc.
2069 Golfside Drive
Ypsilanti, Michigan 48197

Re: K970782
Imaging Jet System
Dated: October 10, 1997
Received: October 20, 1997
Regulatory class: II
21 CFR §876.1500/Product code: 78 KOG
21 CFR §892.1600/Product code: 78 JAB

Dear Dr. Shan:

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): K970782

Device Name: Imaging Jet System

Indications For Use:

The Image Jet System provides physicians with a three dimensional image of an endoscope inside a patient.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K970782

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)