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K963354

P191

510 (k) Summary for 5 Star Medical, Inc.

DEVICE NAME

5 Star Medical Endoscope

SEP - 8 1997

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

Saratoga Modular Miniature Endoscope System

DESCRIPTION OF DEVICE

A description of the endoscopes' components is as follows:

Optical Catheters

A rigid mini ureteroscope provides for examination of the lower third of the ureter. Channels are provided for irrigation and instrumentation.

The deflecting tip scopes are available in various lengths (30 to 200 cm) and outer diameters (1.6 to 4.0mm) for visualization and diagnosis of the urethra , bladder(of children), ureters (of adults) and kidney. They can also be used to directly visualize and diagnose conditions in the common bile duct, liver and pancreatic duct. The exploration of the colon can also be accomplished by passing the 5 Star Medical endoscopes through the operating channel of a standard colonoscope. They are available with a working channel, fiberoptic cable connection and device for deflection. Manipulation at the proximal end of the flexible scope activates the deflection of the distal tip.

Optical Handle

The optical handle consists of an eye piece, a barrel and a scope connection. The handle incorporates magnifying optics which can be adjusted for focus with the focusing ring.

Fiber Optic Cables, Adapters and Light Sources

The fiber optic cables consist of a bundle of non-coherent glass fibers. The fiber optic bundle is sheathed. The light source end of the cable is configured to fit various light sources currently available in distribution (e.g. Wolf, Olympus, Storz ACMI and Pentax). The instrument end of the cable is finished with a female ACMI type connector. Light sources which are in common use are compatible with the 5 Star Medical Endoscope. Diagnostic and photo light sources are effective and safe to use with this system. The adapters which are available for use with the fiber optic cable provide for connection to light sources built by Wolf, Olympus, Storz, ACMI and Pentax.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Beverly J. Stewart
President
5 Star Medical, Inc.
4767 Wren Court
Charlottesville, Virginia 22911

SEP - 8 1997

Re: K963354
5 Star Medical Endoscope
Dated: June 1, 1997
Received: June 13, 1997
Regulatory class: II
21 CFR §876.1500
Product codes: 78 FGB, FGC, FAJ, FDA, FTK, GCF, FBN, FGA, FAM, FDT, KOG

Dear Ms. Stewart:

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,

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): K963354

Device Name: Endoscope

Indications For Use:

Direct visualization of G.I. - G.U. system using additional accessories to perform various diagnostic and therapeutic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K963354

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)