



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

LSI Solutions, Inc.
Mr. Christopher A. Klaczyk
Regulatory Compliance Manager
7796 Victor-Mendon Road
Victor, NY 14564

JUL 27 2015

Re: K024301
Trade/Device Name: LSI Endoscope External Accessory
Channel Device and Accessories Product
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC
Dated (Date on orig SE ltr): December 20, 2002
Received (Date on orig SE ltr): December 24, 2002

Dear Mr. Klaczyk,

This letter corrects our substantially equivalent letter of March 24, 2003.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

LSI SOLUTIONS, Inc.
510(k) Premarket Notification
LSI Endoscopic External Accessory Channel and Accessories Product

11. Premarket Notification [510(k)] Summary

Submitted By: LSI SOLUTIONS, Inc.
7796 Victor-Mendon Road
Victor, New York 14564
Phone: (585) 869-6600
Fax: (585) 742-8086
Contact: Christopher A. Klaczyk, Regulatory Compliance Manager

Common Name: Endoscope and/or accessories

Trade Name: LSI Endoscopic External Accessory Channel and Accessories Product

Classification Name: *Endoscope and accessories* (per 21 CFR §876.1500)

Predicate Device: LSI SOLUTIONS Flexible Suture Placement Device and Accessories Product (K011016)

Description: The LSI Endoscopic External Accessory Channel and Accessories Product is a sterile conduit that can be safely attached to common endoscopes. This Endoscopic External Accessory Channel enables the passage of additional endoscopic instruments to enhance the effectiveness of diagnostic and therapeutic interventions.

Intended Use: The LSI Endoscopic External Accessory Channel and Accessories Product is intended for use as a supplemental conduit that attaches to an endoscope to enable improved access during endoscopic procedures.

LSI SOLUTIONS, Inc.
510(k) Premarket Notification
LSI Endoscopic External Accessory Channel and Accessories Product

7. Statement of Indications For Use

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510(k) Number (if known): K024301

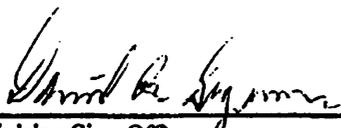
Device Name: LSI Endoscopic External Accessory Channel and Accessories Product

Indications For Use:

The LSI Endoscopic External Accessory Channel and Accessories Product is intended for use as a supplemental conduit that attaches to an endoscope to enable improved access during endoscopic procedures.

(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,
and Radiological Devices
510(k) Number K024301

Prescription Use
(Per 21 CFR 801.109)

(Optional Format 3-10-98)