AUG 6 1998

Attachment 8 - 510(k) Summary
510(k) Premarket Notification - K982287
Aslan Modular Instrument
Aslan Medical Technologies, Ltd.

K982287

510(k) Summary

510(k) Summary

Information supporting claims of substantial equivalence as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "... 510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

NEW DEVICE NAME: ASLAN LAPAROSCOPIC SET

PREDICATE DEVICE NAMES: Circon Snap-In Snap-Out™ Laparoscopic Set
Karl Storz Take Apart™ Laparoscopic Set

510(k) Summary

Device Description

Aslan Modular Instruments comprise a modular line of re-usable instruments consisting of various size shafts, handles of various configurations, and a number of interchangeable tips which can be used in laparoscopic surgery for grasping, cutting, and cauterizing delicate tissues using monopolar electrocautery. The tips and shafts, sized to fit through 5mm, 10mm or 12mm cannulae, range in length from 12cm to 45cm. For ease of cleaning, the tip, together with its actuating rod, can be completely removed from the shaft, and the tip-and-shaft assembly may be completely removed from the handle.

Intended Use

Aslan Modular Instruments are intended to be used by a qualified surgeon for grasping, manipulating, cutting and/or coagulating tissue in endoscopic (videoscopic) procedures.

Indications Statement

Aslan Modular Instruments are intended to be used by a qualified surgeon for grasping, manipulating, cutting and/or coagulating tissue in endoscopic (videoscopic) procedures.

Technological Characteristics

The new laparoscopic set is technologically like the predicate devices. Differences do not raise new questions of safety and effectiveness.

Performance Data

Benchtop evaluations were conducted on each of the instruments in the laparoscopic set to ensure that they met or exceeded all requirements for their intended use (strength of materials, electrical conductivity, ease of cleaning, and ease of use). Where specific standards exist (e.g., for resistance to high voltage in electrocautery use: ANSI/AAMI HF18-1993), each instrument in the laparoscopic set passed the tests without a single failure.

Conclusions

Based on the information provided herein, we conclude that the new laparoscopic instrument set is substantially equivalent to the Predicate Devices under the Federal Food, Drug and Cosmetic Act.

Contact

Thomas J. Hoogeboom, Ph.D.
President
Aslan Medical Technologies, Ltd.
4110 South 9th Street
Kalamazoo, Michigan, USA 49009

Date

July 1, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 6 1998

Thomas J. Hoogeboom, Ph.D.
President
Aslan Medical Technologies, Ltd.
4110 South 9th Street
Kalamazoo, Michigan 49009

Re: K982287
Trade Name: Aslan Sensor Modular Instrument
Regulatory Class: II
Product Code: GCJ
Dated: June 26, 1998
Received: June 30, 1998

Dear Dr. Hoogeboom:

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.

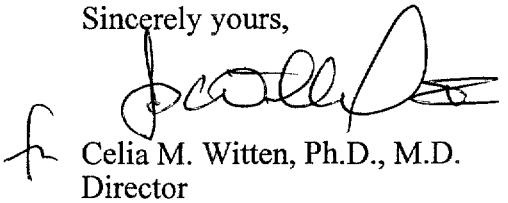
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 5a - Indications for use
510(k) Premarket Notification
Aslan Modular Instrument
Aslan Medical Technologies, Ltd.

K982287

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Device Name: **Aslan Sensor™ Modular Instrument**

Indications for use:

Aslan Sensor™ Modular Instruments are intended to be used by a qualified surgeon for grasping, manipulating, cutting and/or coagulating tissue in endoscopic (videoscopic) 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 General Restorative Devices
510(k) Number K982287

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)