

K070509

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Date: February 15, 2007

Submitter: Name: Baitella AG
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MAR 22 2007

Product: Trade Name: FISSO Holding System
Classification: Class II
Common Name: Endoscope Holder
Classification Name: Neurological Endoscope

Table with 4 columns: Predicate Devices, Name, Manufacturer, K-No.
Armand Endoscope Holder, KLS-Martin L.P., K050051
Neuroview Instrument Holder, Model 300-33, Integra Neurocare LLC, K992006
Abdominal Wall Retractor, Omni-Tract Surgical, K950214

FISSO Holding System is substantially equivalent to the predicate devices since the basic features and intended uses are the same.

Device Description: Table-mounted self-retaining endoscope holder system consisting of stainless steel tubular, articulated arms that are connected to a vertical stand and are freely adjustable within the articulating radius according to the requirements of the particular surgical procedure.

The device is reusable and provided non-sterile. It must be cleaned and sterilized before use.

Intended Use: FISSO Holding System consists of a table-mounted endoscope holder system intended for use by surgeons to hold endoscopes and arthroscopes with a diameter of 4mm to 10mm during general diagnostic and therapeutic procedures.

Performance Data: Design analysis and comparison as well as verification testing confirm that basic functional characteristics are substantially equivalent to the predicate devices cited and raise no new issues of safety and effectiveness.

Conclusion: Based upon the product technical information provided, intended use, and performance information provided in this premarket notification, FISSO Holding System has been shown to be substantially equivalent to current legally marketed predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 22 2007

Baitella AG
% Business Support International
Ms. Angelika Scherp
Regulatory Affairs
Amstel 320-I
Amsterdam, 1017AP
The Netherlands

Re: K070509
Trade/Device Name: FISSO Holding System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 12, 2007
Received: February 22, 2007

Dear Ms. Scherp:

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

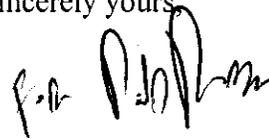
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: FISSO Holding System

Indications for Use:

FISSO Holding System consists of a table-mounted endoscope holder system intended for use by surgeons to hold endoscopes and arthroscopes with a diameter of 4mm to 10mm during general diagnostic and therapeutic procedures. The device is also intended for use by qualified surgeons for holding endoscopes during diagnostic and therapeutic neurologic procedures.



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number 14070509

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)