

AUG 27 1999

K991989

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of Mitaka's knowledge.

Applicant: Mitaka USA, Inc.
2337 Lucky John Drive
Park City, Utah 84060
(435) 649-2236

Contact: Max Sturgis
President

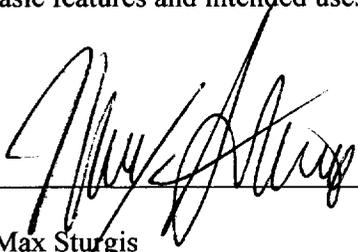
Device Identification: Common Name:
Endoscope Holder

Trade Name: (optional)
Point Setter

Indication: The Mitaka Point Setter is intended for use by qualified surgeons for holding rigid and flexible endoscopes during diagnostic and therapeutic neurologic procedures.

Device Description: The Mitaka Point Setter is a manual/pneumatic surgical device composed of materials commonly used in medical devices for a wide range of applications.

Substantial Equivalence: The Mitaka Point Setter is substantially equivalent to the predicate device since the basic features and intended uses are the same.

Signed: 
Max Sturgis
President



AUG 27 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Max Sturgis
President
Mitaka USA, Inc.
2337 Lucky John Drive
Park City, Utah 84060

Re: K991989
Trade Name: Mitaka Point Setter
Regulatory Class: II
Product Code: GWG
Dated: June 7, 1999
Received: June 14, 1999

Dear Mr. Sturgis:

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.

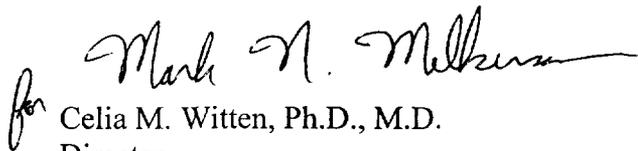
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 – Mr. Max Sturgis

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,

for Mark N. Melkerson

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

Mitaka USA

510(k) Number (if known): K991989

Device Name: Mitaka Point Setter

Indications for Use: This instrument is intended for use by qualified surgeons for holding rigid and flexible endoscopes during diagnostic and therapeutic neurologic procedures.

for Mark N. Milkenstein
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991989

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)