 K090792

Mitaka Kohki Co., Ltd.

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JUL - 6 2009

Section 5. 510(k) Summary

Date Prepared:	March 20, 2009
Contact Person:	Max Sturgis, President Mitaka USA, Inc. 2337 Lucky John Drive Park City, UT 84060 (435) 649-2236 maxsturgis@q.com
Trade Name:	**UniARM**
Common Name:	Endoscope Holder
Classification Name:	**Endoscope and/or Accessories** **Device Class 2** **Regulation Number: 876.1500 & 882.1480** **Product Classification GWG** **Additional Product Classification KOG, & GCJ**

1. The legally marketed devices to which Mitaka Kohki is claiming equivalence:

Mitaka Point Setter – K984355 Endoscope holder, K991989 Neuro Dia and clinical use
Kroner - Wingman Scope Holder - K000663 General Surgery, K973543 General Surgery

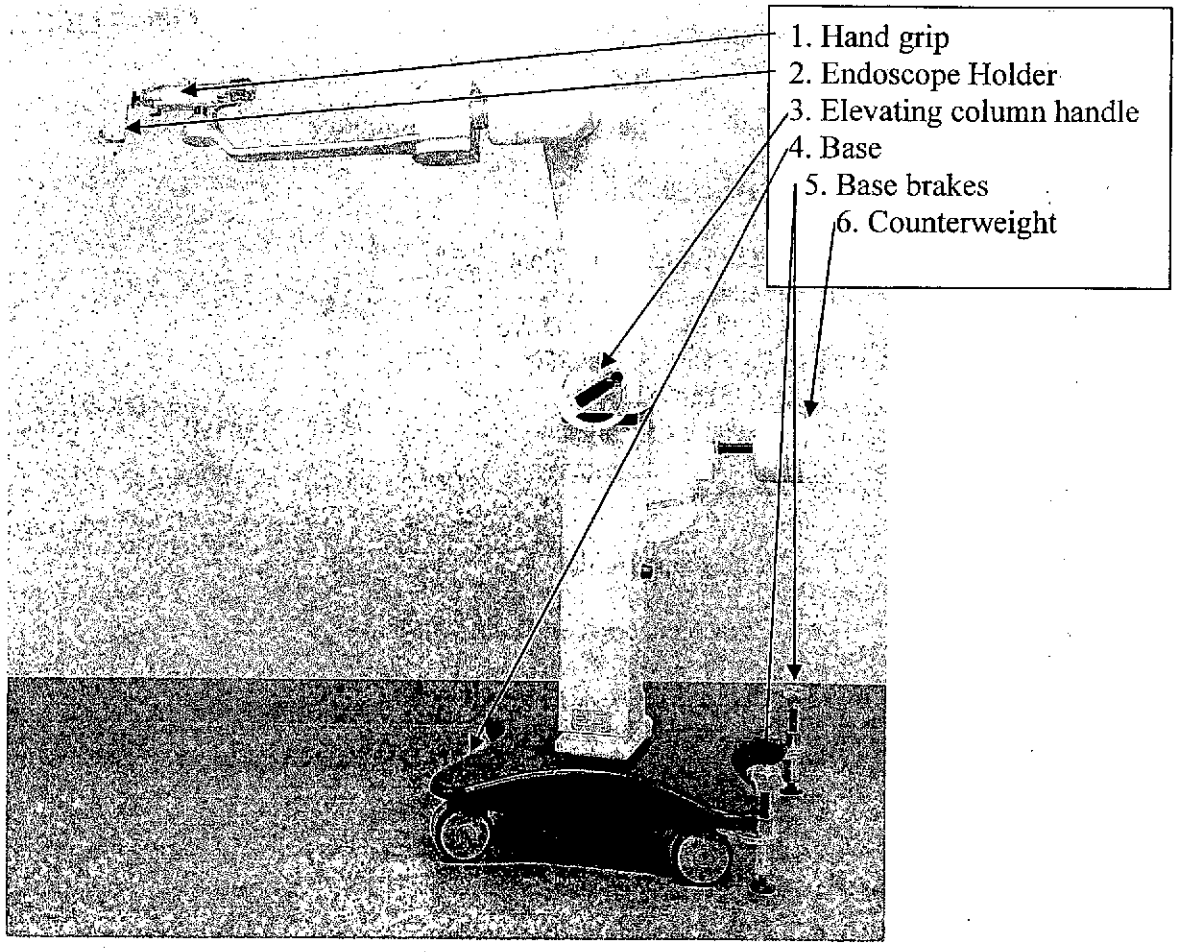
2. Description of the Mitaka UniARM:

Summary: the Mitaka UniARM device is for use in holding medical devices in surgery such as neuro endoscopes, general endoscopes, and hand held instruments. It is a balanced device using pneumatic brakes that can be released from a single switch near the endoscope or hand held instrument. Often referred to as a third arm it provides a stable platform to hold an endoscope or hand held instrument allowing the surgeon the use of his two arms. The system can be released by the push of one button and fixes with the release of that button. A second button is depressed by the palm as a safety device.

A. Design configuration:
   a. Brakes – Uses fail safe clutches which when activated by Nitrogen pressure from operating room source allow the clutches to turn freely. When the nitrogen pressure is released by surgeon controlled button the pressure escapes and the clutches hold tight.
   b. Mechanics – The UniARM uses a system of counterweights that allow the surgeon to balance the weight of an endoscope or instrument. This counter balancing allows greater ease and precision in repositioning the endoscope or instrument.

c. Base – The system is mounted to a base with four wheels so it can be positioned at the side of patient. Base brakes hold the base securely. The base has mounted an elevating unit to allow arm to be raised and lowered for optimal positioning.

UniARM



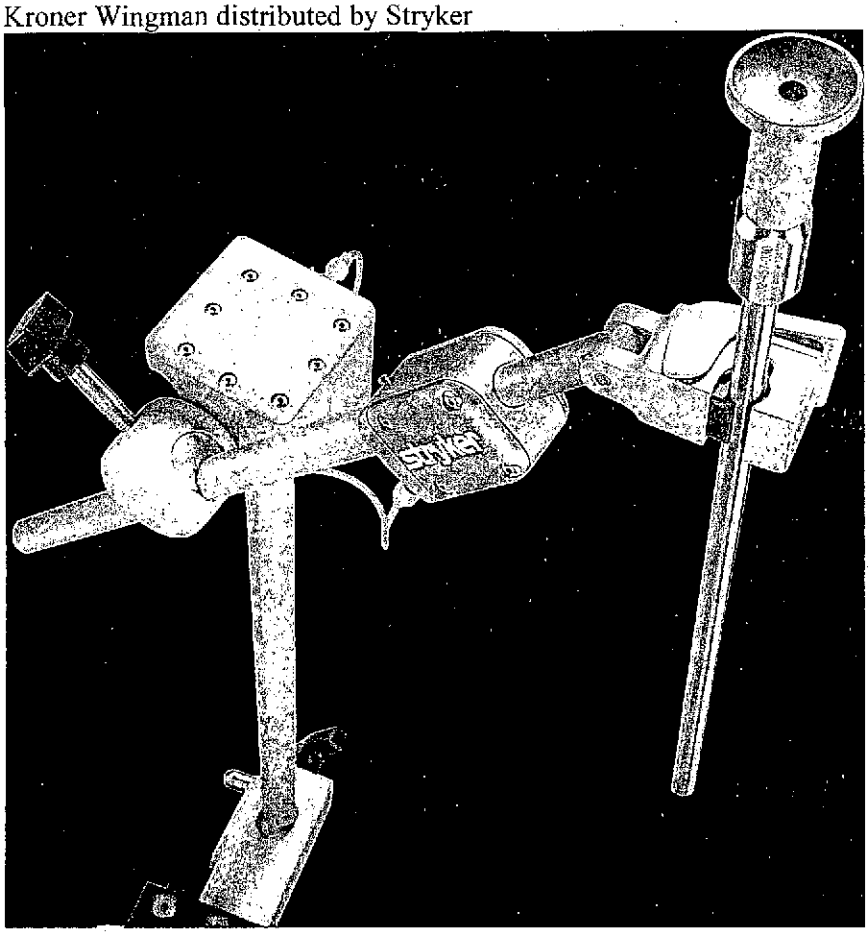
3. Intended use: The **UniARM** is for use in holding medical devices in surgery such as neuro endoscopes, general endoscopes, and hand held instruments.

4. Technological characteristics compared to the Mitaka Point Setter – K984355 and the Kroner Scope Holder - K000663 (Distributed by Stryker under "Wingman" name).

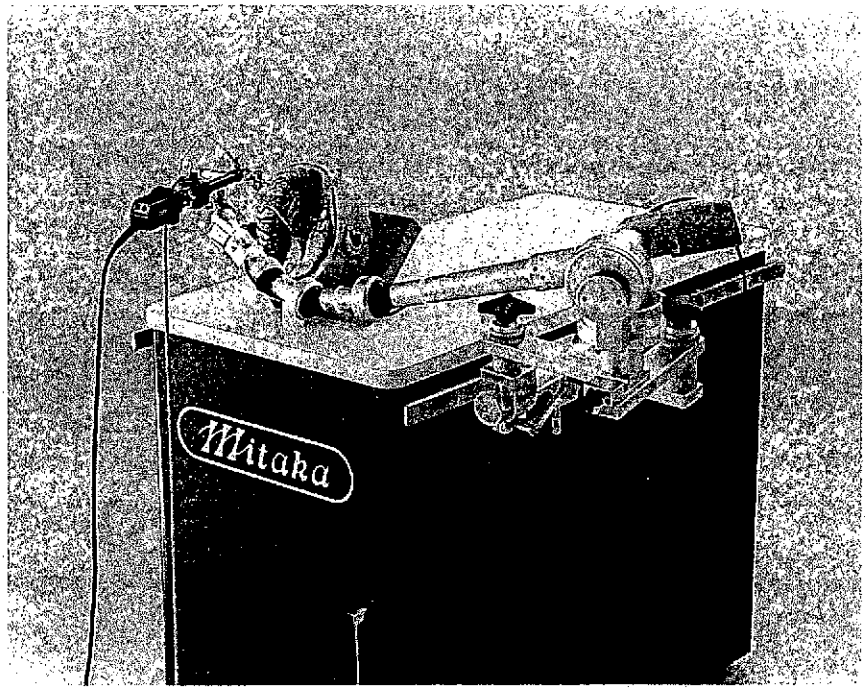
Both the Mitaka Point Setter (manufactured by Mitaka Kohki Co.) and the Kroner scope holder are used to hold endoscopes and other hand held instrumentation. Both perform the same third hand function. Below see table with device comparison and below that see photos of Mitaka Point Setter and Kroner – Wingman scope holder.

Function	Kroner – Wingman	Mitaka Point Setter	Mitaka UniARM
Balance	Adjustable Spring	Arm is balanced but surgeon holds weight of endoscope system.	Arm balances both endoscope and holding arm perfectly
Power source	Electric & Pneumatic	All pneumatic	All Pneumatic
Attaches to:	OR table rail	OR table rail	Sits on roll able Base
Holds	Endoscopes and hand instruments	Endoscopes and hand instruments	Endoscopes and hand instruments

Kroner Wingman distributed by Stryker



Mitaka Point Setter



5. **Non-clinical performance data:** The system goes through a test procedure using a force gauge to test all brake holding power. The same force measurement system is used on the Point Setter. See section 18.

6. **Clinical Performance:** The system has been tested in operating rooms with patients for over one year in Japan where it is manufactured.

7. **Conclusion:** Clinical, performance, and non-clinical validation compared to Kroner-Wingman and Mitaka Point Setter show that the devices are substantially equivalent to the UniARM. The UniARM merely offers improvements in reach, holding power, and convenience.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mitaka Kohki Co., Ltd.
% Mitaka USA, Inc.
Mr. Maxwell Sturgis
President
2337 Lucky John Drive
Park City, Utah 84060

JUL - 6 2009

Re: K090792
Trade/Device Name: UniARM
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ, GWG
Dated: June 2, 2009
Received: June 3, 2009

Dear Mr. Sturgis:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 (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 Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

 K090792

Revised Indications for Use

510(k) Number (if known):

Device Name: **UniARM**

Indications for Use: The **UniARM** is for use in holding medical devices such as endoscopes and retractors in surgery.

Prescription Use __X__ AND/OR Over-The-Counter Use N/A____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090792

Revised 4-1