

APR 21 2008

**Marionette™ SA
(Surgical Assistant)
Summary**

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 information included in this document is accurate and complete to the best of KSLLC's knowledge.

Applicant: Kinetic Surgical LLC
6215 Ferris Square, Ste. 100
San Diego, CA 92121

Contact Person: Jim Caputo
President

Date of Summary: April 15, 2008

Device Name: Marionette™ SA

Common Name: Grasper, Scissors, & Dissector

Regulatory Class: Class II

Predicate Device: Endolink True Movement system
(K043541)
Microline Incorporated Re-New Laparoscopic Instruments
(K962119)
Cambridge Laparo-Angle
(K061425)

Intended Use: The Marionette™ SA is intended for use by surgeons for grasping, dissection, and tissue cutting during laparoscopic surgical procedures.

Device Description: The Marionette™ SA is a manually operated, articulating mechanical surgical device. It is primarily composed of stainless steel, anodized aluminum and Delrin. The instrument provides for the one handed control (left or right hand) of the positioning/repositioning of an instrument that

includes the ability to change disposable/reusable tips for grasping, dissection, and tissue cutting during laparoscopic surgical procedures. The device is sold non-sterile to the hospital institution to be cleaned and sterilized on site prior to each use. Some accessories that support the device are sold sterile and are single use components.

Substantial Equivalence:

The Marionette™ SA is substantially equivalent in application and function to the Endolink True Movement System, Cambridge Laparo-Angle and the Microline Re-New laparoscopic instrument.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kinetic Surgical, LLC
% Mr. Jim Caputo
President
6215 Ferris Square, Suite 100
San Diego, California 92121

APR 21 2008

Re: K072811

Trade/Device Name: Marionette™ SA (Surgical Assistant)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 7, 2008
Received: April 9, 2008

Dear Mr. Caputo:

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 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.

Page 2 – Mr. Jim Caputo

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

APPENDIX D



Indications For Use

510(k) number: K072811

Device Name: Marionette™ SA (Surgical Assistant)

The Marionette™ SA is intended for use by surgeons for grasping, dissection, tissue cutting during laparoscopic surgical procedures.

Prescription Use (Per 21 CFR 801 Subpart D)

OR

Over-The-Counter (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)

(Division Sign-Off)

Neil R. Ogle for rxm

Division of General, Restorative, and Neurological Devices

510(k) Number K072811