K033578

JUL 1 1 2005

510(k) Summary

Submitter: ClearMedical, Inc.
1776 136th Place NE
Bellevue, WA 98005

Contact: Gene Lim
Ph: (425) 460-2779
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Date: June 21, 2005

Trade name: ClearMedical Reprocessed Reloadable Linear Cutters and Staplers

Common name: Reloadable Linear Cutters and Linear Staplers

Classification name: Manual surgical instrument for general use (21 CFR 878.4800)

Product code: GCJ – Laparoscope, General & Plastic Surgery

Predicate device: K020779 – Endopath and Proximate Linear Cutters and Staplers

Device description: The Reprocessed Reloadable Cutters deliver two double-staggered rows of titanium staples while dividing the tissue between the rows. The reloadable cutters may be reloaded during a single procedure, up to a maximum number of firings per instrument as stated in the product insert.

The Reprocessed Reloadable Staplers deliver two double-staggered rows of titanium staples to approximate internal tissues. The reloadable cutters may be reloaded during a single procedure, up to a maximum number of firings per instrument as stated in the product insert.

Intended use: The ClearMedical Reprocessed Reloadable Cutters are intended for transection, resection, and creation of anastomoses in gastrointestinal, gynecologic, thoracic, and pediatric surgery.

The ClearMedical Reprocessed Reloadable Staplers are intended for the resection of tissues in the alimentary tract and in thoracic surgery.

Technological characteristics:	Reprocessed reloadable cutters and staplers are used devices that are cleaned, inspected, tested, packaged, and sterilized for an additional single patient use. The technological characteristics of design, material, and functional performance of reprocessed reloadable cutters and staplers are unchanged and remain equivalent to the predicate devices.
Test data:	Validation of cleaning, performance, packaging, and sterilization together with biocompatibility testing demonstrate reprocessed clip reloadable cutters and staplers perform as intended and are safe and effective.
Conclusion:	Based on information provided in this submission, ClearMedical Reprocessed Reloadable Cutters and Staplers are substantially equivalent to the identified predicate devices and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2005

Clear Medical Incorporated
Mr. Mike Kovacs
1776 136th Place Northeast
Bellevue, Washington 98005

Re: K033578
Trade/Device Name: Reprocessed Reloadable Cutters, Staplers, and Appliers Models, TLC55/TCT55, TLC75, TCT75, TLC10/TCT10,TL455, Proximate Linear Staplers TL30, TL60, TX30B, and TX60B
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: NLL
Dated: May 27, 2005
Received: May 31, 2005

Dear Mr. Kovacs:

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.

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D.
Acting 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): K033578

Device Name: Reprocessed Reloadable Cutters and Staplers

Indications for Use:

Reloadable Cutters

The ClearMedical Reprocessed Reloadable Cutters are intended for transection, resection, and creation of anastomoses in gastrointestinal, gynecologic, thoracic, and pediatric surgery.

Reloadable Staplers

The ClearMedical Reprocessed Reloadable Staplers are intended for the resection of tissues in the alimentary tract and in thoracic surgery.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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