JUL 27 2004

K033592

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

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This 510(k) Summary details sufficient information to provide an understanding of the basis for a determination of substantial equivalence. For convenience, the summary is formatted pursuant to 21 CFR §807.92. This section may be used, as presented, to provide a substantial equivalence summary to anyone requesting it from the Agency.

21 CFR §807.92 a (1)

Submitter: ClearMedical, Inc
1776 136 Place NE
Bellevue, Washington 98005
Contact person: Mike Kovacs
Ph: 425-460-2718
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Date prepared: 29 June 2004

21 CFR §807.92 a (2)

Trade name: Reprocessed Used, Disposable Endoscopic Scissors and Graspers

Common name: Laparoscopic/Endoscopic Surgical Instruments
Classification name: 79GCJ, Manual Laparoscopic Surgical Instruments
79GEI, Endoscopic Electrosurgical Instruments

21 CFR §807.92 a (3)

Identification of predicate(s): Substantial equivalence for the *Reprocessed Used, Disposable Endoscopic Scissors and Graspers* is based on its similarities to the predicate devices, Ethicon *Endoscopic Surgical Instruments* (K930933) 22 June 2003. The *Reprocessed Used, Disposable Endoscopic Scissors and Graspers* is substantially equivalent to the predicates in intended use, material, design, performance, and physical characteristics.

21 CFR §807.92 a (4)

Device Description-parts and function/concept: The Reprocessed SUD (*Reprocessed Used, Disposable Endoscopic Scissors and Graspers)* is a sterilized SUD. The reprocessed Endopath endoscopic instruments are sterile, single patient use instruments that have a rotating insulated shaft and are designed for use through appropriate surgical trocars. The rotation knob located on the handle rotates the shaft 360 degrees in either direction. Some instruments have a monopolar cautery connector extending from the top of the handle and can be used for electosurgery when properly attached to standard cautery cables and appropriate generators. Other instruments have rachet handles, which allow the instrument jaws to be locked in place. The instrument jaws or scissor blades are activated by compression and release of the ring handles. See instructions for use for complete mode of operation

details. The Reprocessed SUD (*Reprocessed Used, Disposable Endoscopic Scissors and Graspers)* is cleaned using EtO sterilization.

21 CFR §807.92 a (5)
Intended use and relationship to predicate(s): The *Reprocessed Used, Disposable Endoscopic Scissors and Graspers* is indicated for use in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transaction of tissue.

CFR §807.92 a (6)
Technological characteristics and relationship to predicate(s):
The *Reprocessed Used, Disposable Endoscopic Scissors and Graspers* is similar in design, material, intended use and technological characteristics to the predicate devices.

21 CFR §807.92 b
This substantial equivalence is based on similarities to the predicate devices in terms of intended use, material, and technological characteristics.

21 CFR §807.92 c
In accordance with the specifications of this subsection, this summary (two pages) is its own section, and has been clearly identified as such.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2004

Mr. Mike Kovacs
Vice President, Engineering and Production
ClearMedical, Inc.
1776 136th Place, NE
Bellevue, Washington 98005

Re: K033592
Trade/Device Name: Reprocessed Used, Disposable Endoscopic Scissors
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 29, 2004
Received: June 30, 2004

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication Statement

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510(k) Number (if known): K033592

Device Name: *Reprocessed Used, Disposable Endoscopic Scissors*

Indications for Use

The ClearMedical *Reprocessed Used, Disposable Endoscopic Scissors and Graspers* have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transaction of tissue..

Prescription Use_____X_____ OR Over-The-Counter Use
(Per 21 CFR 801.109) Optional Format 1-

(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

510(k) Number K033592

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