MEDICAL SALES COMPANY

PRODUCT DEVELOPMENT DIVISION

MAR 17 2000

PREMARKET NOTIFICATION

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Prepared: December 15, 1999

01.	Submitter (and specification developer):	Medical Sales Company P O Box 540314 101 N. 700 West North Salt Lake UT 84054
02.	Packager:	Medical Techniques LC 125 N. 400 West, Suite C North Salt Lake UT 84054
03.	Sterilizer:	Griffith Micro Sciences -- SLC Div. 5725 W. Harold Gatty Rd. Salt Lake City UT 84116
04.	Contact Person:	Tom Haslam, Sr., Owner
	Telephone:	800-292-4056
05.	Trade Name:	Umbilical Cord Clamp
06.	Common Name:	Umbilical Cord Clamp
07.	Classification Name:	Clamp, Umbilical
08.	Product Code:	85 HFW
	Device Class:	Class II
09.	Performance Standards:	No performance standards have been officially adopted by the FDA.
09.	Predicate Device(s):	K990737, et al, submissions, information attached, which were determined to be SE

3063 South Davis Blvd * Bountiful, Utah * Telephone 801-295-6023 * Fax 801-296-5963

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

10. Description: Umbilical cord clamp, injection-molded plastic, blue, single-use, disposable, packaged, sterile (sterilized by 100% EtO gas).

11. Intended Use: The device is a sterile, single-use, disposable umbilical cord clamp, used to clamp over the umbilical cord of a newborn at delivery. The device is used to hold the cord securely and prevent blood loss and seepage as the cord dries and shrinks after the birth, prior to and after cutting.

12. Summary of the Technological Characteristics of This Device Compared to the Predicate(s):

    There are no substantive changes in materials, basic configuration and function, method of manufacture or packaging, or sterilization between this device and its predicates.

13. Summary of Nonclinical Tests and Results:

    The device has been tested by an independent lab for biocompatability (cyctotoxicity, hemolysis) with no problems noted. The clamps will be subjected to QC upon receipt, during/after manufacture, and prior to release.

14. Conclusion:

    The function and use of this device is no different than that of the predicates, as well as similare devices, marketed since pre-amendment.

Signed: Thomas J. Haslam Dated: 12-16-99

Thomas J. Haslam, Owner
MEDICAL SALES COMPANY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2000

Medical Sales Co.
c/o Mr. John E. Lincoln
J.E. Lincoln and Associates
P. O. Box 154
Tooele, UT 84074

Re: K994367
Umbilical Cord Clamp
Dated: February 17, 2000
Received: February 22, 2000
Regulatory Class: II
21 CFR §884.4530/Procode: 85 HFW

Dear Mr. Lincoln:

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 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). 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 (Premarket 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 requirements, 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.

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) 594-4591. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K994367

Device Name: Umbilical Cord Clamp

Indications For Use:

Sterile, single-use, disposable umbilical cord clamp, used to clamp over the umbilical cord of a newborn at delivery. The device is used to hold the cord securely and prevent blood loss and seepage as the cord dries and shrinks after the birth, prior to and after cutting.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use XX
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994367

(Optional Format 1-2-96)