JAN 2 2 2004

## 510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K033403

### 1. Submitter's Identification:

T.S.Medical
208 Carter Drive, Suite 12A
West Chester, Pa 19382 USA

Date Summary Prepared: October 23, 2003

### 2. Name of the Device:

a. Proprietary: T.S. Medical Circumcision Clamp
b. Common Name: Mogen Style Circumcision Clamp
c. Classification Name: Circumcision Clamp
d. Device Class: 21 CFR 884.4530, Class II
e. Classification Panel: Obstetrical and Gynecological Panel
f. Product Code: HFX

### 3. Predicate Device Information:

The TS Medical Circumcision Clamp is identical in materials, design, and intended use to the circumcision clamps marketed by Tri-State Medical Corp. (K935491) and the Mogen Circumcision Clamp marketed by Mogen Circumcision Instruments, Ltd. (grand fathered). Each of these clamps is in the "mogen- style" and is constructed of medical stainless steel. All are intended for infant circumcision and are reusable.

### 4. Device Description:

The TS Medical Circumcision Clamp is a stainless steel, reusable, and "mogen-style" circumcision clamp. The T.S. Medical Circumcision Clamps are constructed of stainless steel that meets the requirements of ASTM-F 899, Stainless Steel Bullet, Bar and Wire for Surgical Instruments.

The following size will be offered: 2.5 mm.

5. **Intended Use:**

The TS Medical Circumcision Clamp is intended to be used in a medical procedure to compress the foreskin of the penis during circumcision of a male infant.

6. **Comparison to Predicate Devices:**

The TS Medical Circumcision Clamp to substantially equivalent in materials, design, and intended use to the predicate devices.

7. **Discussion of Non-Clinical Tests Performed:**

Non-clinical tests were not performed.

8. **Discussion of Clinical Tests Performed:**

Clinical tests were not performed.

9. **Conclusions:**

The TS Medical Circumcision Clamp is safe and effective for it's intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2004

T.S. Medical, Inc.
% Ms. Carolann Kotula
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
GREAT NECK NY 11021

Re: K033403
Trade/Device Name: T.S. Medical Circumcision Clamp
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: 85 HFX
Dated: October 23, 2003
Received: October 24, 2003

Dear Ms. Kotula:

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 one of the following numbers, based on the regulation number at the top of the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 4

# Indications for Use

510(k) Number (if known): **K033403**

Device Name: **T.S. Medical Circumcision Clamp**

Indications For Use: A Circumcision Clamp is an instrument used in a procedure to compress the foreskin of the penis during circumcision of male infant or child

Prescription Use ___X____ ~~AND~~/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



David A. Lepmann

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033403