APR - 9 2004

Attachment 1
K040052

## 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

### 1. Submitter's Identification:

Fine Surgical Instruments, Inc.
741Peninsula Blvd.
Hempstead, NY 11550
**Tel: 516-292-7400**
**Fax: 516-292-7484**

Date Summary Prepared: January 9, 2004

### 2. Name of the Device:

a. Proprietary: Fine Surgical Circumcision Clamp
b. Common Name: Gomco 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 Fine Surgical Circumcision Clamp is identical in materials, design, and intended use to the Centurion® CirClamp™ circumcision clamps marketed by Tri-State Medical Corp. (K890897). The Fine Surgical clamp differs from the predicate in that it will be offered non-sterile for further processing and a larger size will be available.

### 4. Device Description:

The Fine Surgical Gomco Circumcision Clamp is a disposable medical device that is constructed of chrome plated brass. The device will be sold non sterile for further processing (ie. Packaging and sterilization) by the final distributor. We do not intend to sell these devices directly to the end user.

### 5. Intended Use:

The Fine Surgical Circumcision Clamp is intended to be used in a medical procedure to compress the foreskin of the penis during circumcision of a male infant or child.

## 6. Comparison to Predicate Devices:

| | Fine Surgical Gomco Circumcision Clamp | Centurion® CirClamp™ |
|---|---|---|
| Intended Use | Infant and Child circumcision | Infant Circumcision |
| Sizes Available | Extra Small: 1.1 cm<br>Newborn: 1.3 cm<br>Infant: 1.45 cm<br>Child: 1.6 cm | Extra Small: 1.1 cm<br>Newborn: 1.3 cm<br>Infant: 1.45 cm |
| Materials | Chrome-Plated Brass | Chrome-Plated Brass |
| Re-Use | No, disposable | No, disposable |
| Sterility | Non-Sterile | Sterile |

## 7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Non Clinical testing was not performed

## 8. Discussion of Clinical Tests Performed:

Clinical testing was not performed

## 9 Conclusions:

The Fine Surgical Gomco-Style 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

APR - 9 2004

Fine Surgical Instruments, Inc.
c/o Ms. Carolann Kotula
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd.
GREAT NECK NY 11021

Re: K040052
Trade/Device Name: Fine Surgical Circumcision Clamp
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: 85 HFX
Dated: January 9, 2004
Received: January 12, 2004

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 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 3**



**510(k) Number (if known):** K040052

**Device Name:** Fine Surgical Instruments Gomco-Style 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)**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

David A. Lepson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040052