APR - 1 2005

EXIBIT#1

510(K) SUMMARY

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

Date Summary Prepared: December 21, 2004

The assigned 510(k) Number is K043533

(1). Submitter's Identification

Surgical Design, Inc.
7351-D Lockport Place
Lorton, Va 22079
Tel#(703)541-0196
Fax#(703)541-0197

Contact Name: Mohammad Bashir – Quality Control

(2) NAME OF THE DEVICE:

a. ***Proprietary: Surgical Design Circumcision Clamp***
b. ***Common Name: Gomco Style Circumcision Clamp***
c. ***Classification Name: Circumcision Clamp***
d. ***Device Class: 21CFR 884.4530, [redacted]***
e. ***Classification Panel: Obstetrical and Gynecological Panel***
f. ***Product Code: HFX***

(3) PREDICATE DEVICE INFORMATION:

The Surgical Design Circumcision Clamp is identical in material, design and intended use to the Centurion ® CirClamp™ Circumcision clamps marketed by Tri-State Medical corp.(K890897). The Surgical Design clamp differs from predicate in that it will be offered Non Sterile for further processing and a larger size will be available.

EXIBIT#1

(4) DEVICE DESCRIPTION:

The Surgical Design 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(i.e. Packaging and Sterilization) by the Final Distributors. We do not intend to sell these devices to the end users.

(5) INTENDED USE:

The Surgical Design 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:

	Surgical Design Gomco Circumcision Clamp	Centurion® CirClamp™
Intended Use	Infant and Child circumcision	Infant Circumcision
Sizes Available	Extra Small: 1.1 CM Newborn: 1.3 CM Infant: 1.45 CM Child : 1.6 CM	Extra Small: 1.1 cm Newborn: 1.3 cm 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:

Surgical Design 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 - 1 2005

Mr. Mohammed Bashir
Director Quality Control
Surgical Design, Inc.
P.O. Box 625
NEWINGTON VA 22122

Re: K043533
Trade/Device Name: Surgical Design
Circumcision Clamp
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic
specialized manual instrument
Regulatory Class: II
Product Code: HFX
Dated: February 28, 2005
Received: March 1, 2005

Dear Mr. Bashir:

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

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

K043533/5

IX. Indications for Use: [Separate Page]

510(k) Number: ~~NA~~ K043533

Device Name: Surgical Design Circumcision Clamp

A circumcision clamp is used in a circumcision procedure to compress the foreskin of the penis during circumcision of a male infant or child.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043533