K030891

JUN 17 2003

510(K) Summary

Surgistar 2400-LSK

Submitter: Surgistar, Inc.
6068 Corte Del Cedro
Carlsbad, CA. 92009

Telephone: (760) 431-7400
Fax: (760) 431 6768

Contact person: Jonathan Woodward

Date Prepared: March 19, 2003

Device Trade Name: Surgistar Microkeratome Blade,
Model No. 2400-LSK

Device Common Name: Keratome Blade, Microkeratome Blade

Device Classification Name: Keratome (Blade Only)

Classification Regulation No.: CLASS 1, Reserved

Classification Panel: OPHTHALMIC

Product Code: 86 HNO

Legally marketed device to which we are claiming equivalence:

Predicate Device Name: PLANCON MICROLAMELLAR
KERATOME; LSK-1 Keratome (Blade only)

Manufacturer: PLANCON INSTRUMENTS (Moria, Inc.)

510(k) Number: K970377

Description of the Device:

The Surgistar 2400-LSK is a replacement microkeratome blade for the Moria LSK-ONE Keratome. The blade consists of a 420 low carbon stainless steel blade and a plastic holder attached to the blade. The 2400-LSK blades are single-use, disposable blades.

Intended use of the device:

The Surgistar 2400-LSK Microkeratome is indicated for use as a replacement blade in the Moria LSK-ONE Keratome. The surgical indication for use is in patients undergoing surgery requiring initial lamellar resection of the cornea.

Summary of Technological characteristics of device compared to predicate device.

CHARACTERISTICS	MORIA LSK-ONE BLADE (PREDICATE)	SURGISTAR LSK-2400 BLADE
Intended Use	As Indicated	Same
Target population	As Indicated	Same
Performance	Indication for use with the LSK-ONE Microkeratome.	Same
Blade Material	Low Carbon Stainless Steel	Same
Biocompatibility	For Stainless Steel Blades	Same
Mechanical Safety	Assured	Same
Sterilization Method	Gamma Irradiation	Same

Performance tests and conclusions:

1. Dimensional Equivalency – Measurements of the predicate device are substantially equivalent to the specifications established by Surgistar.

2. Sharpness – Sharpness tests indicate the Surgistar 2400-LSK performs equivalently to the Moria LSK-ONE.

3. Keratome Fit – Fit tests with the Moria LSK-ONE Keratome head demonstrated that the Surgistar 2400-LSK fit was acceptable.

4. Non-clinical porcine eye studies demonstrated equivalent corneal lamellar sections between the Surgistar 2400-LSK and the Moria LSK-ONE.

5. Conclusion – The Surgistar 2400-LSK was demonstrated to be substantially equivalent to the predicate Moria LSK-ONE.

(Premarket Notification [510(k)] Number)_____

510(K) Summary

Surgistar 2410-CB

Submitter:	Surgistar, Inc. 6068 Corte Del Cedro Carlsbad, CA. 92009
Telephone:	(760) 431-7400 Fax: (760) 431 6768
Contact person:	Jonathan Woodward
Date Prepared:	March 19, 2003
Device Trade Name:	Surgistar Microkeratome Blade, Model No. 2410-CB
Device Common Name:	Keratome Blade, Microkeratome Blade
Device Classification Name:	Keratome (Blade Only)
Classification Regulation No.:	CLASS 1, Reserved
Classification Panel:	OPHTHALMIC
Product Code:	86 HNO

Legally marketed device to which we are claiming equivalence:

Predicate Device Name:	CARRIAZO BARRAQUER MICROKERATOME (Blade only)
Manufacturer:	MORIA, Inc.
510(k) Number:	K981741

Description of the Device:

The Surgistar 2410-CB is a replacement microkeratome blade for the Moria Carriazo Barraquer Keratome. The blade consists of a 420 low carbon stainless steel blade and a plastic holder attached to the blade. The 2410-CB blades are single-use, disposable blades.

Intended use of the device:

The Surgistar 2410-CB Microkeratome blade is indicated for use as a replacement blade in the Moria Carriazo Barraquer Keratome. The surgical indication for use is in patients undergoing surgery requiring initial lamellar resection of the cornea.

Summary of Technological characteristics of device compared to predicate device.

CHARACTERISTICS	MORIA C-B BLADE (PREDICATE)	SURGISTAR LSK-2400 BLADE
Intended Use	As Indicated	Same
Target population	As Indicated	Same
Performance	Indication for use with the Carriazo Barraquer Microkeratome.	Same
Blade Material	Low Carbon Stainless Steel	Same
Biocompatibility	For Stainless Steel Blades	Same
Mechanical Safety	Assured	Same
Sterilization Method	ETO	Same

Performance tests and conclusions:

1. Dimensional Equivalency – Measurements of the predicate device are substantially equivalent to the specifications established by Surgistar.

2. Sharpness – Sharpness tests indicate the Surgistar 2410-CB performs equivalently to the Moria C-B Microkeratome blade.

3. Keratome Fit – Fit tests with the Moria Carriazo Barraquer Keratome head demonstrated that the Surgistar 2410-CB fit was acceptable.

4. Non-clinical porcine eye studies demonstrated equivalent corneal lamellar sections between the Surgistar 2410-CB and the Moria C-B Microkeratome blade.

5. Conclusion – The Surgistar 2410-CB was demonstrated to be substantially equivalent to the predicate Moria C-B Microkeratome blade.

(Premarket Notification [510(k)] Number)_____

510(K) Summary

Surgistar 2420-M2

Submitter:	Surgistar, Inc. 6068 Corte Del Cedro Carlsbad, CA. 92009
Telephone:	(760) 431-7400 Fax: (760) 431 6768
Contact person:	Jonathan Woodward
Date Prepared:	March 19, 2003
Device Trade Name:	Surgistar Microkeratome Blade, Model No. 2420-M2
Device Common Name:	Keratome Blade, Microkeratome Blade
Device Classification Name:	Keratome (Blade Only)
Classification Regulation No.:	CLASS 1, Reserved
Classification Panel:	OPHTHALMIC
Product Code:	86 HNO

Legally marketed device to which we are claiming equivalence:

Predicate Device Name:	CARRIAZO BARRAQUER II MICROKERATOME (Blade only)
Manufacturer:	MORIA, Inc.
510(k) Number:	K002191

Description of the Device:

The Surgistar 2420-M2 is a replacement microkeratome blade for the Moria Carriazo Barraquer II Keratome. The blade consists of a 420 low carbon stainless steel blade and a plastic holder attached to the blade. The 2420-M2 blades are single-use, disposable blades.

Intended use of the device:

The Surgistar 2420-M2 Microkeratome blade is indicated for use as a replacement blade in the Moria Carriazo Barraquer II Keratome also known as the M2. The surgical indication for use is in patients undergoing surgery requiring initial lamellar resection of the cornea.

Summary of Technological characteristics of device compared to predicate device.

CHARACTERISTICS	MORIA CARRIAZO BARRAQUER II MICROKERATOME BLADE (PREDICATE)	SURGISTAR M2-2420 BLADE
Intended Use	As Indicated	Same
Target population	As Indicated	Same
Performance	Indication for use with the Carriazo Barraquer II Microkeratome.	Same
Blade Material	Low Carbon Stainless Steel	Same
Biocompatibility	For Stainless Steel Blades	Same
Mechanical Safety	Assured	Same
Sterilization Method	ETO	Same

Performance tests and conclusions:

6. Dimensional Equivalency – Measurements of the predicate device are substantially equivalent to the specifications established by Surgistar.

7. Sharpness – Sharpness tests indicate the Surgistar 2420-M2 performs equivalently to the Moria M2 Microkeratome blade.

8. Keratome Fit – Fit tests with the Moria Carriazo Barraquer II Keratome head demonstrated that the Surgistar 2420-M2 fit was acceptable.

9. Non-clinical porcine eye studies demonstrated equivalent corneal lamellar sections between the Surgistar 2420-M2 and the Moria M2 Microkeratome blade.

10. Conclusion – The Surgistar 2420-M2 was demonstrated to be substantially equivalent to the predicate Moria M2 Microkeratome blade.

(Premarket Notification [510(k)] Number)_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2003

Surgistar, Inc.
c/o Jonathan Woodward
President
6068 Corte Del Cedro
Carlsbad, CA 92009

Re: K030891
Trade/Device Name: Surgistar Microkeratome Blade Models No. 2400-LSK, 2410-CB, and 2420 M2
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: HNO
Dated: March 19, 2003
Received: March 21, 2003

Dear Mr. Jonathan Woodward:

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) 594-4613. 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,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030891

Device Name: Surgistar 2420-M2 Microkeratome Blade

Indications for Use

The Surgistar 2420-M2 Microkeratome is indicated for use as a replacement blade in the Moria M2 Microkeratome. The surgical indication for use is in patients undergoing surgery requiring initial lamellar resection of the cornea.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

[signature]
...sion Sign-Off)
...sion of Ophthalmic Ear,
...e and Throat Devises
...0(k) Number K030891

(Optional Format 3-10-98)

510(k) Number (if known): K030891

Device Name: Surgistar 2400-LSK Microkeratome Blade

Indications for Use

The Surgistar 2400-LSK Microkeratome is indicated for use as a replacement blade in the Moria LSK-ONE Keratome. The surgical indication for use is in patients undergoing surgery requiring initial lamellar resection of the cornea.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K030891

(Optional Format 3-10-98)

510(k) Number (if known): K030891

Device Name: Surgistar 2410-CB Microkeratome Blade

Indications for Use

The Surgistar 2410-CB Microkeratome is indicated for use as a replacement blade in the Moria Carriazo Barraquer Microkeratome. The surgical indication for use is in patients undergoing surgery requiring initial lamellar resection of the cornea.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K030891

(Optional Format 3-10-98)