NOV 1 6 1999

K992978

510(K) Summary
(As required by 21 CFR 807.92)

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

Contact person:
Jonathan Woodward

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

Trade name: Surgistar Microkeratome Blade
Common name: Microkeratome Blade
Classification name: Microkeratome Blade

Legally marketed device to which we are claiming equivalence:
Chiron Vision Corp Automatic Corneal Shaper Surgical Instrument (BLADE ONLY)
510(k) Number – K941550

Description of the Device:
Replacement Stainless Steel Blade for Chiron Automatic Corneal Shaper Blade

Intended use of the device:
Replacement Blade for Chiron Automatic Corneal Shaper Blade

Summary of Technological characteristics of device compared to predicate device.(Section 807.92(a)(6)

CHARACTERISTICS	AUTOMATIC CORNEAL SHAPER BLADE ONLY(PREDICATE-)	Surgistar MICROKERATOME Prod No. 2200
INTENDED USE	FOR PERFORMING LAMELLAR RESECTIONS OF THE CORNEA	SAME
OPERATION PRINCIPLE	BLADE IS HELD IN ELECTRICALLY DRIVEN OCILLATING HEAD (PROVIDED BY ORIGINAL EQUIPMENT MANUFACTURER Eg CHIRON) WHICH GUIDES BLADE ACROSS CORNEA	SAME
PATIENT CONTACT PORTION OF DEVICE	BLADE	SAME
MATERIALS	LOW CARBON STAINLESS STEEL	SAME
STERILIZATION METHOD (BLADE)	EO	RADIATION-GAMMA

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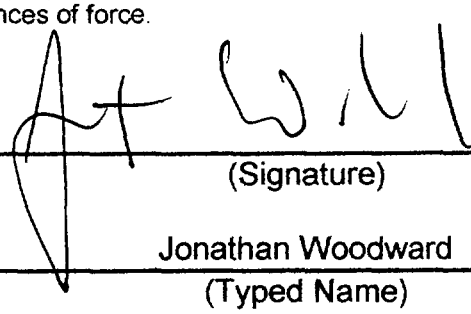
DIMENSIONAL & SHARPNESS EQUIVALENCY CHART

ATTRIBUTE	CHIRON ACS BLADE AS MEASURED	SURGISTAR MICRO KERATOME BLADE SPECIFICATION
LENGTH	0.448"	0.445" +/- .005
WIDTH	0.313"	0.313" +/- .003
THICKNESS	0.0102"	0.010" +/- .0003
BEVEL	11 TO 12.5 DEG	11.5 Deg +/- 1 Deg
MOUNTING HOLE LENGTH	0.2805	0.2805 +/-.0005
MOUNTING HOLE WIDTH	0.0866	0.0866 +/-.0005
MOUNTING HOLE RADIUS	0.0433	0.0433 +/- .0005
SHARPNESS*	4 to 7 OZ	5.5 OZ +/- 1.5 OZ

* As measured in ounces of force.



(Signature)

Jonathan Woodward

(Typed Name)

November 1,.1999

K 992978

(Premarket Notification [510(k)] Number)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 1999

Mr. Jonathan Woodward
President
Surgistar, Inc.
6068 Corte Del Cedro
Carlsbad, CA 92009

Re: K992978
Trade Name: Microkeratome Blade
Regulatory Class: I
Product Code: 86 HNO
Dated: October 13, 1999
Received: October 14, 1999

Dear Mr. Woodward:

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 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) 594-4613. 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" (21 CFR 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/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known): K992978

Device Name: SURGISTAR MICROKERATOME BLADE

Indications For Use:

Statement of indication for use

The Surgistar Microkeratome is indicated for use as a replacement blade in the Chiron Vision Automatic Corneal Shaper Surgical Instrument (ACS).
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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K992978

Prescription Use √ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)