K043150

JAN 3 1 2005

510(k) Summary for the Amadeus II Epikeratome

Name and Address of Sponsor

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Name and Address of Manufacturer

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Name and Address of Official Correspondent

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Device Name

Device trade name: Amadeus II Epikeratome
Common/Classification name: Keratome

Classification, Panel and Product Code

Device Classification:	Class I (reserved), HNO
Reviewing Panel:	Ophthalmic Devices

Intended Use

The Amadeus II Epikeratome is intended for use in performing lamellar corneal resections. This is the same intended use as previously cleared for the Amadeus microkeratome, K993190.

Indications for Use

The Amadeus II Epikeratome is intended for use in the separation of epithelium from the cornea in preparation for subsequent surgical procedures on the denuded cornea.

Substantial Equivalence

The Amadeus II Epikeratome is substantially equivalent to the Amadeus Microkeratome, K993190, 02/10/2000.

Device Description

The Amadeus II Epikeratome is a modification of the ACCM/Amadeus Microkeratome, which is firmly established in the market for several years. In the course of a product update, the designs of blade and blade holder have been modified to provide surgeons with the option to perform Epi-LASIK.

The surgical principles of the Amadeus II Epikeratome and its predicate device are essentially identical. To perform a lamellar corneal resection, the cornea is held in position by means of a suction ring, and vacuum is applied to increase intraocular pressure to a level allowing the epikeratome blade to move across the cornea in a mode similar to that of a carpenter's plane. The corneal flap is made by the same operating principle as in the predicate device, i.e., a blade is advancing and simultaneously oscillating horizontally and perpendicular to the advancement direction. A Control Unit provides power and a controlled vacuum for fixing the eye.

The corneal flap created by the epikeratome consists of the entire epithelium, while in the predicate device it consists of the entire epithelium plus parts of the stroma. This difference in flap structure is obtained by modifications of the blade and the blade holder.

Like its predicate device, the Amadeus II Epikeratome comprises three major groups of components:

a) A Handpiece, incorporating the Suction Unit, the Blade Holder, the Epikeratome Epi-LASIK Blade and the Motor Unit. The Handpiece offers several safety features designed to prevent product malfunction or incorrect use, and allows the surgeon to handle the Epikeratome with only one hand.

b) A Control Unit with touch-screen interface, managing the epikeratome's cutting action and the automatic documentation of the chosen cutting parameters and user interface dialogs.

c) Two footswitches that serve to actuate and discontinue the epikeratome cutting procedure. The standard actuation footswitch serves to initiate suction and the epikeratome cutting action.

Disposable components of the Amadeus II Epikeratome system are 1) a sterile plastic epikeratome blade and 2) a sterile vacuum tubing kit. Additionally, an autoclavable instrument tray is provided for sterilization.

Performance Data:

Design controls (e.g., risk assessment, design verification and design validation), as well as clinical data from an animal study, were used to demonstrate that the changes made to the device are safe and effective.

Rationale for Substantial Equivalence

- Intended use of the Amadeus II Epikeratome is the same as that of the predicate device.
- The operating principle of the Amadeus II Epikeratome is very similar to the one of the predicate device and based on the same cutting kinematics.
- The safety features of the Amadeus II Epikeratome are the same as those offered by the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2005

SIS Surgical Instrument Systems Ltd.
c/o Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.
13 Red Fox Lane
Littleton, CO 80127

Re: K043150
Trade/Device Name: Amadeus II Epikeratome
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: HNO
Dated: January 11, 2005
Received: January 12, 2005

Dear Mr. Walls:

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) 827-8910. 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/industry/support/index.html.

Sincerely yours,

A. Ralph Rosenthal

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

Indications for Use Statement

510(k) Number (if known):

Device Name: Amadeus II Epikeratome

Indications For Use: The Amadeus II Epikeratome is intended for use in the separation of epithelium from the cornea in preparation for subsequent surgical procedures on the denuded cornea.

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)

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

510(k) Number K043150