K032910

AUG 3 0 2004

SECTION 11

510(k) SUMMARY

This 510(k) summary of safety and effectiveness for the SCHWIND eye-tech-solutions Carriazo Pendular Microkeratome is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: SCHWIND eye-tech-solutions

Address: Mainparkstrasse 6-10
Kleinostheim 63801
Germany

Manufacturer: SCHWIND eye-tech-solutions GMBH & CO. KG
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Germany 63801

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Telephone: +49/6027 508273

Contact Person: Mr. William T. Kelley

Telephone: 949-292-8477
Fax Number: 509-479-4840.

Preparation Date: August 2004
(of the Summary)

Device Name: Carriazo Pendular Microkeratome

Common Name: Keratome (microkeratome)

Classification: 21 CFR 886.4370
Class I
Product Code: HNO
Panel: 86

Predicate devices: Carriazo Barraquer Microkeratome M2 (K981741); Hansatome Microkeratome (K972808); Plancon Microlamellar Keratome (K980924); Hansatome Excellus (K021640); UltraShaper System (K990227); Visitone 20-10 Microkeratome (K014000).

Indications: The Carriazo Pendular Microkeratome is indicated for shaving the cornea prior to lamellar (partial thickness) transplant or to create a flap in the cornea.

Performance Data: A clinical study in 200 eyes was conducted to collect data to primarily provide reasonable assurance of the safety and effectiveness of the Carriazo-Pendular Microkeratome in a clinical setting.
Moreover, an additional study has been performed at another site (Dr. Maria Arbelaez) with special focus on flap thickness, flap diameter and hinge size with different cutting heads and suction rings as declared in the product specification. This study provides evidence of the validity of labeled flap thicknesses and diameters which the different cutting heads are capable of producing.
The studies include the consistent and predictable performance of the device in meeting the clinically-selected parameters.

The differences in specifications between the Carriazo-Pendular (CP) Microkeratome and its predicates (e.g., the Carriazo-Barraquer or CB) have been evaluated. Selected differences in specifications include head/ring coupling (the CP couples automatically; predicates use manual coupling); the CP vacuum is adjustable to 675 mm Hg; the predicates are constant at 625 mm Hg); the CP has a double-headed vacuum pump and the predicates single-headed vacuum pumps; the CP electronically detects and signals a cable break; the predicates lack this feature); shape of the blade (CP is curved; the predicates are straight); the CP has a ball-shaped cutting head; the predicates are straight; at the stop in final position - the CP is automatic; the predicates are not; the CP has right and left eye rings, the predicates do not; and the CP head is guided by two separate mains; the predicates by a single pivot on the ring only and the head can move up and down during the cut which can result in micro-scattering on the stromal bed). Many specifications of the Carriazo-Pendular Microkeratome and its cited predicates are substantially the same, e.g., hinge width, diameter of the ring, conformance to EN standards and meeting CE Mark requirements.

The tissue-contact materials used in the fabrication of the Carriazo-Pendular Microkeratome have been shown to be biocompatible and the sterilization methods have been validated to a sterility assurance level of at least 10^{-6} and the packaging has been tested to assure its performance in maintaining the sterility of the components supplied sterile.

Summary:

The claim of substantial equivalence of the SCHWIND Carriazo-Pendular Microkeratome is based on clinical studies, comparisons of its specifications, intended use, and other information with the claimed predicates.

The results of clinical studies constitute valid scientific evidence (as described in 21 CFR 860.7) which provides reasonable assurance that the Carriazo-Pendular Microkeratome is safe and effective for its intended use. Moreover, the results of the studies also provide valid scientific evidence that the observed differences in specifications between the Carriazo-Pendular Microkeratome and its predicates are not significant in terms of the clinical performance of the device. Further, the results of clinical studies corroborate its claim of substantial equivalence to the cited predicate microkeratomes.

CONCLUSION: Based on the information in this notification SCHWIND eye-tech-solutions believes that Carriazo Pendular Microkeratome is substantially equivalent to the claimed predicates under conditions of use described in the labeling of the Carriazo-Pendular Microkeratome.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2004

Schwind Eye-Tech-Solutions
% William T. Kelley
23832 Via Monte
Coto de Caza, CA 92679

Re: K032910
Trade/Device Name: Carriazo Pendular Microkeratome
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: HNO
Dated: September 18, 2003
Received: September 22, 2003

Dear Mr. Kelley:

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

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K032910

Device Name: Carriazo Pendular Microkeratome

Indications for Use Statement:

The Carriazo Pendular Microkeratome is indicated for shaving the cornea prior to lamellar (partial thickness) transplant or to create a flap in the cornea.

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The Counter Use ___
(Per 21 CFR 801.109)

Clay R. Butterworth

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

510(k) Number K032910