FEB 18 2004

510(k) SUMMARY
20/10 Perfect Vision FemTec™ Laser Microkeratome

1. SUBMITTER INFORMATION

A.	Company Name:	20/10 Perfect Vision GmbH
B.	Company Address:	Am Taubenfeld 21/1 69123 Heidelberg Germany
C.	Company Phone: Company Fax:	49-6221-7502-110 49-6221-7502-121
D.	Contact Person:	Dr. Frieder Loesel CEO, 20/10 Perfect Vision GmbH
E.	Date Summary Prepared:	January 30, 2004

2. DEVICE IDENTIFICATION

A.	Classification Name:	1. Keratome 2. Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
B.	Trade/Proprietary Name:	FemTec™ Laser Microkeratome
C.	Device Classification:	Class II (per 21 CFR 878.4810)
D.	Product Code:	HNO & GEX

3. SUBSTANTIAL EQUIVALENCE

The FemTec™ Laser Microkeratome is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Pulsion FS Laser Keratome	Intralase Corp.	K013941	February 27, 2002
Hansatome Microkeratome	Bausch & Lomb Surgical	K010260	April 27, 2001

The materials, basic scientific concepts, and physical properties of the FemTec Laser Microkeratome are similar to those of the Intralase Pulsion FS Laser Keratome (and the indications for use are identical), and the indications for use for the FemTec Laser Microkeratome are identical to those of the Hansatome Microkeratome.

4. DEVICE DESCRIPTION

The FemTec Laser Microkeratome is intended for use in the creation of a corneal flap by producing short bursts of laser pulses, with each laser pulse having a duration on the order of 500 to 1000 femtoseconds ("fs", 10^{-15} seconds). Microscopic gas bubbles, which form as a result of the laser induced optical breakdown (LIOB), are created adjacent to each other at a pre-determined depth in the cornea. It is this continuous layer of gas bubbles that create the lamellar corneal dissection plane just like a mechanical microkeratome blade. The FemTec Laser Microkeratome creates a flap under very low vacuum (250 mbar), and delivers the laser energy directly to the stromal layer of the cornea through a disposable PMMA contact lens, referred to as the Patient Interface (PI).

5. INDICATIONS FOR USE

The FemTec™ Laser Microkeratome is indicated for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea

6. TECHNOLOGICAL CHARACTERISTICS

The 20/10 Perfect Vision FemTec™ Laser Microkeratome has technological characteristics very similar to those of the Intralase Pulsion FS Laser Keratome. The design, materials, and characteristics of the FemTec™ Laser Microkeratome are similar to those of the Pulsion FS Laser Keratome. The differences between the FemTec™ Laser Microkeratome and the Pulsion FS Laser Keratome are insignificant and do not affect the safety or effectiveness of the device.

7. PERFORMANCE DATA SUMMARY

The FemTec™ Laser Microkeratome has been designed and will be tested to applicable safety standards. In addition, the FemTec™ Laser Microkeratome was found to perform equivalently to the Hansatome Microkeratome with respect to the creation of a corneal flap in an *ex* vivo study.

8. CONCLUSIONS

20/10 Perfect Vision GmbH has demonstrated through its evaluation of the FemTec™ Laser Microkeratome that the device is equivalent to the predicate devices with respect to intended use, technological characteristics, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2004

20/10 Perfect Vision Optische Gerate GmbH
c/o Ms. Carol Patterson
Patterson Consulting Group
21911 Erie Lane
Lake Forest, California 92630

Re: K033354
Trade/Device Name: FemTec™ Laser Microkeratome
Regulation Number: 21 CFR 878.4810, 886.4370
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology; Keratome
Regulatory Class: II
Product Code: GEX, HNO
Dated: January 30, 2004
Received: February 3, 2004

Dear Ms. Patterson:

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) 594-4659. 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,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033354

Device Name: FemTec™ Laser Microkeratome

Indications For Use: The FemTec™ Laser Microkeratome is indicated for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the 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)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033354