

JUN 19 2002

**Hnasatome Excellus Microkeratome****510(k) SUMMARY  
(per 21 CFR §807.92)**

Submitter's Name: Bausch & Lomb  
Address: 3365 Tree Court Industrial Blvd.  
St. Louis, MO 63122

Telephone #: (636) 226-3183  
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Official Correspondent: Dennis Pozzo  
Regulatory Affairs Specialist

Date Summary Prepared: May 15, 2002

Device Name/  
Proprietary name: Hansatome® Excellus™ Microkeratome

Classification/Common Name Keratome

Class: I

Panel: Ophthalmic

Product Code: HNO

The marketed device(s) to which substantial equivalence is claimed: Hansatome® Microkeratome

**PRODUCT DESCRIPTION:**

The Hansatome® Excellus™ Microkeratome is a precision-manufactured instrument indicated for use in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea. It functions identically to the existing Hansatome Microkeratome in that the cutting head rotates about a pivot pin. Propulsion is via a rolling gear within the head which engages with an arcuate gear rack affixed to the suction ring. In addition, the Hasatome Excellus Power/Suction Supply Unit includes 1) a vacuum regulator to allow the physician to set vacuum prior to surgery, 2) a vacuum tank that provides reserve vacuum in the event the vacuum pump fails or power is interrupted during the course of surgery, and 3) a battery pack back-up power supply to the microkeratome motor in the event power is interrupted during the course of surgery. The microkeratome's LCD also contains a back-lit display so the User can read the LCD display in low/no light conditions.

## Substantial Equivalent Basis

The Hansatome® Excellus™ Microkeratome is substantially equivalent to the Hansatome® Microkeratome (K972808 and K010260), see Comparison Matrix below.

### COMPARISON MATRIX

#### SIMILARITIES

<b>CHARACTERISTICS</b>	<b>Current Hansatome Microkeratome</b>	<b><i>PROPOSED</i> Hansatome Excellus Microkeratome</b>
Intended use	Lamellar resection of the cornea preceding LASIK surgery or other treatment requiring initial lamellar resection of the cornea	Lamellar resection of the cornea preceding LASIK surgery or other treatment requiring initial lamellar resection of the cornea
Operating Principle	Electrically driven oscillating blade housed in a head which guides the blade across the cornea within controlled parameters.	Electrically driven oscillating blade housed in a head which guides the blade across the cornea within controlled parameters.
Patient contact portion	<ul style="list-style-type: none"> <li>• Suction Ring</li> <li>• Microkeratome Head</li> <li>• Blade</li> </ul>	<ul style="list-style-type: none"> <li>• Suction Ring</li> <li>• Microkeratome Head</li> <li>• Blade</li> </ul>
Materials <ul style="list-style-type: none"> <li>• Suction ring</li> <li>• Microkeratome Head</li> <li>• Blade</li> </ul>	<ul style="list-style-type: none"> <li>• Stainless Steel</li> <li>• Stainless Steel</li> <li>• Low Carbon Stainless Steel</li> </ul>	<ul style="list-style-type: none"> <li>• Stainless Steel</li> <li>• Stainless Steel</li> <li>• Low Carbon Stainless Steel</li> </ul>
Keratome Mechanism <ul style="list-style-type: none"> <li>• Suction ring/w gear</li> <li>• Microkeratome head thickness plate</li> <li>• Electric motor</li> <li>• Control mechanism</li> <li>• Cutting Principle</li> </ul>	<ul style="list-style-type: none"> <li>• Single arcuate gear rack with temporal pivot pin</li> <li>• 3 interchangeable heads with fixed thickness</li> <li>• DC powered 6-9 volts</li> <li>• Footswitch</li> <li>• Blade oscillation</li> </ul>	<ul style="list-style-type: none"> <li>• Single arcuate gear rack with temporal pivot pin</li> <li>• 3 interchangeable heads with fixed thickness</li> <li>• DC powered 6-9 volts</li> <li>• Footswitch</li> <li>• Blade oscillation</li> </ul>

**COMPARISON MATRIX**

**DIFFERENCES**

<b>CHARACTERISTICS</b>	<b>Current Hansatome Microkeratome</b>	<b><i>PROPOSED</i> Hansatome Excellus Microkeratome</b>
Power Switch	Power Switch is on front of power supply	Power Switch is on back of power supply
Front Panel Labeling	Symbology and verbiage on front panel.	Symbology only on front panel.
Vacuum Pump	Less efficient pump, can only operate at elevations up to 6500 feet above sea level.  The vacuum pump is listed with safety agencies.	More efficient pump, can operate at elevations up to 7000 feet above sea level.  The vacuum pump is not listed with safety agencies.
Power/Suction Supply Unit	Not UL Listed	UL Listed



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUN 19 2002**

Bausch & Lomb, Inc.  
c/o Mr. Dennis Pozzo  
Regulatory Affairs Specialist  
3655 Tree Court Industrial Blvd.  
St. Louis, MO 63122-6694

Re: K021640  
Trade/Device Name: BAUSCH & LOMB Hansatome® Excellus™  
Microkeratome  
Regulation Number: 21 CFR 886.4370  
Regulation Name: Keratome  
Regulatory Class: Class I  
Product Code: 86 HNO  
Dated: May 17, 2002  
Received: May 20, 2002

Dear Mr. Pozzo:

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 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

510(K) Number -

Device Name: Hansatome® Excellus™ Microkeratome

**Indications for Use:**

The Bausch & Lomb Hansatome Excellus Microkeratome is a precision-manufactured instrument indicated for use in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  OR Over-the-Counter Use

*Marsha R. Burke Nicholas*  
(Division Sign-Off)

510(k) Number K021640

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Bausch & Lomb Surgical