SECTION 14

SUMMARY OF SAFETY AND EFFECTIVENESS

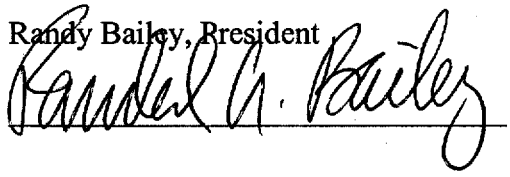
This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

a. Applicant:

VisiJet, Inc.
188 Technology Drive
Suite D
Irvine, CA 92718
(949) 450-1660
(949) 453-9652 (fax)

b. Contact Person: Randy Bailey, President



c. Date Summary Prepared: March 26, 1999

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: VisiJet™ Hydrokeratome™- Model 50

b. Classification Name: Keratome

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company:	Barron Precision Instruments, L.L.C.
Device:	Barron Microkeratome System Model B2000
510(k):	K973317

Company:	Medjet, Inc.
Device:	HydroBrush
510(k):	K971078
Company:	Hansa Research and Development, Inc.
Device:	Automatic Corneal Shaper (ACS)
510(k):	913697

4. **A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

The VisiJet Hydrokeratome - Model 50 is a non-oscillating, non-mechanical microkeratome which utilizes a continuous high-velocity beam of sterile water for injection to effect a lamellar resection of the cornea. The major elements of this microkeratome are a system console, a footswitch and a handpiece with interchangeable suction rings. The operating principle of the water beam microkeratome is based on the ability to create high levels of static hydraulic pressure that is directed across the cornea, effecting a lamellar resection.

5. **Statement of intended use:**

The VisiJet Hydrokeratome is intended for use in performing anterior lamellar circular corneal resections.

6. **Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.**

A summary of the comparative technological characteristics between the VisiJet Hydrokeratome and comparable legally marketed devices immediately follows this page.

7. Brief summary of nonclinical tests and results:

The VisiJet™ Hydrokeratome™ has been designed and will be tested to applicable safety standards. All components in contact with tissue are manufactured from known biocompatible material. All motors are UL approved. The specifications and intended use of the VisiJet Hydrokeratome are the same or very similar to predicate devices. In addition, the VisiJet Hydrokeratome was found to perform equivalently to the predicate devices, the Baron Microkeratome System, Automatic Corneal Shaper (ACS) and the Medjet Hydrobrush, and as intended in all cases. Therefore, the technological differences between the VisiJet Hydrokeratome and the predicated devices do not raise any new issues of safety, effectiveness, or performance of the product.

Comparative Technological Characteristics

CHARACTERISTICS	Barron – Microkeratome System	Hansa - Automatic Corneal Shaper	Medjet, Inc. – HydroBrush	*VisiJet™ Hydrokeratome ™*
Intended Use	Partial Anterior Circular Lamellar Corneal Resections	Lamellar Corneal Resections	Corneal Epithelial Removal	Lamellar Corneal Resections
Operating Principle	Electrically driven oscillating blade	Electrically driven oscillating blade	High-velocity water beam	High-velocity water beam
Suction Ring	1 Fixed Height Suction Ring (Disposable – Stainless Steel)	Adjustable Height Suction Ring (Reusable Stainless Steel)	N/A	Suction-applanation Ring (Disposable – polysulfone)
Blade Drive Source	Electric Motor 9V DC (Disposable)	Electric Motor 12V DC (Reusable)	Electric Motor (Reusable)	Electric motor 12V DC (Reusable)
Thickness Control	Fixed Depth Keratome Head (130u, 160u, or 180u)	Thickness Plates	Angle of impingement on flat plate	Clear applanation plate that is part of the suction-applanation rings (140u, 160u, 180u, 200u)
Blade Speed	Blade Oscillation 20,000 RPM	Blade Oscillation 7,500 RPM	NA	NA
Blade/Fluid Beam Angle	25°	25°	7 - 9°	0°
Blade Movement	Reciprocating Sideways	Reciprocating Sideways	Manual, Variable	Non-reciprocating Tranlsation
Blade Material	Stainless Steel	Stainless Steel	High-velocity fluid beam (Sterile solution or WFI); 35 micron cross-section	High-velocity fluid beam (Sterile solution or WFI); 35 micron cross-section
Flap Diameter	Fixed at 8 or 9.5 mm	Variable at 9 mm	N/A	8 - 10 mm
Flap Width	Unknown	Unknown	N/A	Variable, programmable and determined by user. Between 0 - 10 mm
Keratome Head Movement	Manual	Automatic		Automatic
Console Details				
Electrical	Universal AC - 85V to 260V	110/120 AC		Universal AC - 85V to 260V
Vacuum Pump	DC Powered	AC Powered		DC Powered
Blade Height Verification	At factory with Optical Comparator	Clinic Measured with Microscope		At factory with Optical Comparator
Foot Controls	DC Powered	DC Powered		DC Powered

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 20 2000

Visijet, Inc.
c/o Judy F. Gordon, D.V.M.
ClinReg Consulting Services, Inc.
18732 Saginaw
Irvine, Ca 92614

Re: K991124
Trade Name: VisiJet™ Hydrokeratome™ Model 50
Regulatory Class: I Reserved
Product Code: 86 MYD
Regulation: 886.4370
Dated: September 15, 2000
Received: September 15, 2000

Dear Dr. Gordon:

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) 594-6413. 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 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/dsma/dsmamain.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

SECTION 6

INDICATIONS FOR USE

The VisiJet Hydrokeratome is indicated for use in patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K991124