SEP 9 2002

K022833

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k): **Benjamin Biomedical, Inc.**
3125 Tyrone Blvd.
St. Petersburg, FL 33710
Phone: 727-343-5503
Fax: 727-343-4637

Contact Person: Joe Morrison

Date of Summary: July 2, 2002

Trade Name: Benjamin ENVOY Phaco Handpiece

Classification Name: Unit, Phacofragmentation

Predicate Device: Storz Premiere ® Microsurgical System K946227

Intended Use:

As an accessory for the Storz Premiere phacoemulsification system, the Benjamin ENVOY Hand Piece intended for use in cataract surgery to breakup, emulsify and extract the cataract.

Device Description:

1. General: The Envoy is a Class II phacofragmentation handpiece device per 886.4670 of 21 CFR. The handpiece uses a piezoelectric transduction method to longitudinally oscillate a cutting tip (not included with the device) at a resonant frequency of 28 kHz. The device has integral colinear irrigation and coaxial aspiration fluidic pathways.
2. Host Phacofragmentation System: The device is intended as a replacement for the phacofragmentation handpiece used on the Bausch and Lomb Premiere™ and Protégé™ phacofragmentation system consoles. These systems has been commercially available in the U.S. for approximately 10 years. To insure compatibility with the host system, the Envoy handpiece is designed to be equivalent to the original handpiece used on the previously mentioned systems.

PHACO HANDPIECE COMPARISON SUMMARY

PARAMETER	*BENJAMIN ENVOY*	*STORZ PREMIERE™*
Intended use	Phacofragmentation	Same
Design	Piezoelectric Transduction	Same
Materials	Titanium, Silicone, Stainless steel	Same
Operating frequency	28 kHz	Same
Qty. piezocrystals	2	Same
Sterilization method	Steam only	Same
Host system	Premiere™ and Protégé™	Same
Biocompatibility	Meets ISO 10993-1	Same
Patient contact	Indirect (fluids)	Same
Device setup	Connect tubing [1]	Same
	Tip installation [2]	Same
	System connection [3]	Same

[1] Male and Female non-locking luer fittings.

[2] #4-40 UNC-2B threaded connection.

[3] Multi-contact electrical connector.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 2002

Benjamin Biomedical, Inc.
c/o Mr. Mark Job
TUV America, Inc.
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K022833
Trade/Device Name: Benjamin Envoy Phoco Handpiece
Regulation Number: 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: II
Product Code: HQC
Dated: July 2, 2002
Received: August 26, 2002

Dear Mr. Job:

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 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

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 (if known): K022833

Device Name: Benjamin ENVOY Phaco Handpeice

Indications For Use:

As an accessory for the Storz Premiere phacoemulsification system, the Benjamin ENVOY Hand Piece intended for use in cataract surgery to breakup, emulsify and extract the cataract.

(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 K022833

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

(Optional Format 1-2-96)