



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.

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**OFFICIAL
CORRESPONDENT** Penny Northcutt, RAC
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TRADE NAME: Blunt Tip Ex-PRESS Mini Glaucoma Shunt

COMMON NAME: Anterior chamber drainage device

**CLASSIFICATION
NAME:** Implant, Eye Valve

**DEVICE
CLASSIFICATION:** Class II per 21 CFR § 886.3920

PRODUCT CODE 86 (KYF)

PREDICATE DEVICE: Ex-PRESS Mini Glaucoma Shunt
Models R-30, R-50 – K012852

SUBSTANTIALLY EQUIVALENT TO:

The blunt tipped Optonol Ex-PRESS™ Mini Glaucoma Shunt Model R30-1S and R50-1S is substantially equivalent to the predicate Optonol Ex-PRESS Models R30 and R50 Glaucoma Shunt cleared under 510(k) K012852.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The blunt tipped Ex-PRESS Mini Glaucoma Shunts capture aqueous fluid from the anterior chamber of the eye and transport it distally into a conjunctival bleb.

INDICATION FOR USE:

The Blunt Tip Ex-PRESS Mini Glaucoma Shunts are indicated for use in reduction of intraocular pressure in patients with glaucoma where medical and conventional surgical treatments have failed.

TECHNICAL CHARACTERISTICS:

The blunt tipped Ex-PRESS shunts are comprised of a surgical grade stainless steel tube with a rounded tip at the proximal end and a flat angled flange at the distal end. Three transverse reserve openings near the proximal end of the device serve as ports for aqueous fluid in case of occlusion of the primary opening. The flange at the distal end of the devices serves as a reservoir and prevents intrusion into the eye. The external spur in the middle of the implant serves as an anchor and prevents extrusion from the eye.

PERFORMANCE DATA:

Bench testing was conducted per the guidance document "*Guidance for Industry and for FDA Reviewers/Staff Aqueous Shunts - 510(k) Submissions*" – November 16th, 1998.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The Blunt Tip Ex-PRESS Mini Glaucoma Shunt is substantially equivalent to its predicate, the Ex-PRESS Model R30 and R50 Glaucoma Shunt cleared under 510(k) K012852. Both devices have the same indication for use, "reducing intraocular pressure in patients with glaucoma where medical and conventional surgical treatments have failed" and both devices are designed to divert aqueous humor through the implant from the anterior chamber to a subconjunctival space – the bleb. The devices are manufactured from the same materials, using the same processes. The flow restriction mechanisms are identical. Bench testing demonstrates that the devices are functionally equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Optonol Ltd.
c/o Penny Northcutt, RAC
Surgical Regulatory Affairs
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, GA 30097

MAR 13 2003

Re: K030350
Trade/Device Name:
Regulation Number: 21 CFR 886.3920
Regulation Name: Aqueous shunt
Regulatory Class: II
Product Code: KYF
Dated: January 31, 2003
Received: February 3, 2003

Dear Ms. Northcutt:

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 handwritten signature in cursive script that reads "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

Enclosure

510(k) Number (if known): K030350

Device Name: EX-PRESS™ Miniature Glaucoma Family of Implants

Indications for Use:

The EX-PRESS™ Miniature Glaucoma Family of Implants are intended to reduce intraocular pressure in patients with glaucoma where medical and conventional surgical treatments have failed.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K030350

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)