MAR 2 6 2002

K012852

OPTONOL Ltd.
Advancing Medical Technologies

510(k) Summary

SUBMITTER:

Submitted on behalf of:

Company Name:	Optonol, Ltd.
Address:	Communication Center Neve Ilan 90850 Israel
Phone:	(972) 2 5349666
Fax:	(972) 2 5349660

CONTACT PERSON: Richard E. Lippman, O.D., F.A.A.O.
Official Representative and Correspondent
C.L. McIntosh, Inc.
12300 Twinbrook Parkway Suite 230
Rockville, MD 20852

DATE SUMMARY PREPARED: February, 2002

TRADE NAME: Ex-PRESS™ Miniature Glaucoma Implant
COMMON NAME: Eye valve implant

SUBSTANTIALLY EQUIVALENT TO:

The Ex-PRESS™ Miniature Glaucoma Implant is a drainage device for the anterior chamber of the eye to relieve intraocular pressure in patients with glaucoma from failed medical therapy and failed prior surgical intervention. The device is substantially equivalent to the Ahmed Glaucoma Valve (K980657), the OptiMed Glaucoma Shunt (K903462) and the Baerveldt Glaucoma Shunt (K905129 and K955455).

DESCRIPTION of the DEVICE:

The Ex-PRESS™ Miniature Glaucoma Implant device is a stainless steel tube with a blunt needle shaped penetrating tip at one end and a flat, angled flange at the opposite (distal) end. The device is 2.96mm in length and 0.4mm in diameter. The device consists of a tube whose purpose is to capture aqueous fluid from the anterior chamber of the eye and transport the fluid to the distal end and out of the device from which the fluid then moves into a conjunctival bleb. There are three transverse reserve openings near the proximal end of the device to serve as ports for aqueous fluid in case of occlusion of the primary opening. The flange at the distal end of the device serves as

a reservoir and prevents intrusion into the eye. The spur along the bottom of the device prevents extrusion of the device and serves as an anchor. The material of the device is a medical grade stainless steel composition similar in characteristics to other medical implant devices for different indications for use. The device has a stainless steel wire embedded in the tube transverse to the shaft. The purpose of the wire is to restrict the flow passing through the tube.

The device drains aqueous humor from the anterior chamber to relieve excessive intraocular pressure associated with glaucoma. The devices available are the R-30 and R-50 versions that represent different flow characteristics created by different wire diameters welded inside the device. The higher the R- number, the lower the resistance of the device to flow.

INDICATIONS FOR USE:

The Ex-PRESS™ Miniature Glaucoma Implant is intended to reduce intraocular pressure in patients with glaucoma where medical and conventional surgical treatments have failed.

PARAMETERS AVAILABLE:

The Ex-PRESS™ Miniature Glaucoma Implant is available in the following models:
R-30 and R-50.

PRECLINICAL INFORMATION

A battery of preclinical tests including biocompatibility evaluations of intramuscular implantation in rabbits, cytotoxicity tests, animal ocular implantations for safety and tolerance, and an LAL Endotoxicity Test were conducted. In each of these tests the results indicate that the device is non-toxic and the tests indicate that no additional questions of safety are raised.

Physical evaluations including dimensional and surface quality tests, pressure/flow characteristics and structural integrity laboratory bench tests were conducted and determined as acceptable for this device as required in the FDA Guidance: Aqueous Shunts- 510(k) Submissions, November 16, 1998.

CLINICAL TESTING

The clinical study was a prospective, open-label, multi-center study conducted at 14 international sites in 8 countries outside of the United States. There were 113 open-angle glaucoma patients enrolled into 3 protocols: [1] Failed medical therapy or laser trabeculoplasty, [2] Failed medical therapy or laser trabeculoplasty patients who underwent a combined Ex-PRESS™ implantation and cataract surgery and, [3] Failed filtering surgery (trabeculectomy).

The studies were conducted in accordance with the Helsinki Declarations for protection of human subjects and the applicable laws and regulations in each country. Study sites were monitored and managed by Optonol Ltd.

There was a 1-year follow-up period with intermediate scheduled examinations that included tonometry, gonioscopy, and slit-lamp examination.

The safety and effectiveness evaluation was done on a total of 113 patients implanted with the R-30 and R-50, 58 consecutive patients completed a one-year follow-up (defined as Per-Protocol cohort).

The cumulative probability of success for the Per Protocol cohort (R-30 and R-50, n=58) at 1 year (Kaplan-Meier survival curve) was 77%, where success was defined as an IOP reduction greater than 20% from baseline with or without medications (overall success). The cumulative probability of success for the Per Protocol cohort (R-30 and R-50, n=58) at 1 year (Kaplan-Meier survival curve) was 83%, where success was defined as an IOP less than 21 mmHg with or without medications (overall success).

The overall success for the Per Protocol cohort (R-30 and R-50, n=58) at 1 year was 80.4% (weighted mean), where overall success was defined as an IOP reduction greater than 20% from baseline with or without medications. The overall success for the Per Protocol cohort (R-30 and R-50, n=58) at 1 year was 75.9%, where overall success was defined as an IOP < 21 mmHg with or without medications.

The overall average number of glaucoma medications dropped significantly from 1.55 pre-operation to 0.52 one-year post-operation.

Comparison of the Ex-PRESS™ efficacy results to other glaucoma drainage devices based on the literature indicates a comparable safety and efficacy profile.

For safety, the most common adverse events for the intent to treat cohort (n=113) were: additional glaucoma filtering surgery (12.4%), device removal (12.4%), revision of bleb without anti-metabolites (10.6%), device-iris touch (9.7%), clinically insignificant immediate transient post-operative hyphema [<2mm blood in the anterior chamber] (8.9%), post-operative transient shallow anterior chamber (8.0%), post operative hypotony (7.1%), revision of bleb with anti-metabolites (7.1%), tenon cyst (6.2%), corneal complications (6.2%), anterior chamber reformation (5.3%) and device exposure (5.3%). The safety profile of the two versions was similar.

LABELING

The Ex-PRESS™ Miniature Glaucoma Implant is provided sterile to the practitioner in a sealed pouch contained in a sized container surrounded by an outer carton. Included in the package is the disposable device introducer used to assist in implanting the Ex-PRESS™ Device in the eye.

The package comes complete with Instructions for Use for the Practitioner.

The company address is as follows:

Optonol, Ltd.
Communication Center
Neve Ilan 90850
Israel
(972) 2 5349666

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2002

Optonol, Ltd.
c/o CL McIntosh
Richard E. Lippman, O.D., F.A.A.O.
12300 Twinbrook Parkway, Suite 625
Rockville, MD 20852

Re: K012852
Trade/Device Name: Ex-Press Miniature Glaucoma Implant, Models R30 and R50
Regulation Number: 21 CFR 886.3920
Regulation Name: Aqueous shunt
Regulatory Class: Class II
Product Code: KYF
Dated: March 11, 2002
Received: March 12, 2002

Dear Dr. Lippman:

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

Indications Statement

510(k) Number (if known) K012852

Device Name: Ex-Press™ Miniature Glaucoma Implant, Models R30 & R50

Indications for Use:

The Ex-Press™ Miniature Glaucoma Implant is 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 IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Presription Use ✓ OR Over -The-Counter Use _____

(Oprtional Format 1-2-96)

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

510(k) Number K012852