K925636

510(k) SUMMARY Addendum VIII

NOV 12 1993

(1) Submitter Information:

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Contact Person:
A. Mateen Ahmed, Ph. D.
Date of Summary Preparation: August 27, 1993

(2) Device Name: Ahmed™ Glaucoma Valve
a) Proprietary Name: Ahmed™ Glaucoma Valve Model S2
b) Classification Name: Eye Valve Implant

(3) The predicate device to which Substantial Equivalence is demonstrated is the Single Plate Molteno Valve Implant, as manufactured by STAAR Surgical Co., and described in their Premarket Notification, K875099.

(4) Device Description:
The Ahmed™ Glaucoma Valve (AGV) is a new ophthalmic implant for use in intractable glaucoma. The device features a specially engineered, one-way silicone membrane valve system designed to prevent collapse of the anterior chamber (AC) due to hypotony, abnormally low intraocular pressure, and a build-up of excessive intraocular pressure, by venting aqueous humor from the eye. The AGV implant consists of a silicone drainage tube and polypropylene valve body to house the valve membrane and protect it from occlusion by fibrosis. All materials used in the manufacture of the device are of medical grade quality. No toxic substances are used in the manufacturing process. The AGV is terminally sterilized by gamma ray radiation.

The AGV implant begins to control intraocular pressure immediately upon implantation, which is accomplished in a single, simple procedure. The polypropylene valve body is sutured to the episclera, between the superior medial or lateral rectus muscles. The silicone drainage tube is inserted into the anterior chamber at the limbus.

(5) Intended Use:
The AGV is indicated in the management of intractable glaucoma, particularly in cases where previous filtering procedures have failed or are known to provide unsatisfactory results. These may be generally defined as primary neovascular glaucoma and secondary glaucomas associated with clinically elevated IOP's in patients with previously failed glaucoma surgery associated with primary open angle glaucoma, angle closure glaucoma, aphakia and congenital or infantile glaucomas.

6 (a) Technological Characteristics:

From the standpoint of materials, chemical composition and design characteristics, the AGV and the Molteno Implant are similar in that each uses a silicone tube to carry excess aqueous in the eye's anterior chamber to the valve body. The valve body of both devices is made of polypropylene. Additionally, the AGV has a molded silicone water impermeable elastomeric valve membrane. This valve membrane prevents the build-up of excessive intraocular pressure.

Dimensionally, the following comparisons are tabulated for both the AGV valve and Molteno implant:

Valve Implant	Shape	Width (mm)	Length (mm)	Surface Area (mm2)	Height (mm)
Ahmed Model S2 Single Plate	Oval	13	16	184	1.9
Molteno Single Plate	Circular	13	13	135	1.5

	Tube Inner Diameter (mm)	Tube Outer Diameter (mm)
Ahmed Model S2 Single Plate	0.317	0.635
Molteno Single Plate	0.317	0.635

Surgical implantation of the AGV is essentially identical to that of the Molteno Valve, as is the mechanism of encapsulation of the plate by tissue (bleb formation). After the bleb has been formed, the AGV functions in a manner similar to that of Molteno's valve.

(6)(b)(1) Nonclinical Testing:

Nonclinical testing of the AGV encompassed three main types of testing: in vitro laboratory physical testing, in vitro and in vivo biocompatibility testing, and animal implant studies. Aside from destructive testing, no valve failures were observed in any experiments.

In vitro laboratory physical testing involving fluid flow, and pull tests of various types, demonstrate the valve's efficacy and its one-way maintenance of proper pressure, the strength of its physical integrity, and acceptability of the device's functional characteristics.

Sensitive in vitro biocompatibility testing, performed by several methods, demonstrated that the valve and its components are non-toxic, non-irritating, and biocompatible.

An in vivo, long-term and short-term animal studies using rabbits in which the AGV was implanted demonstrated its efficacy with regard to control of IOP, with the fellow eye used as a control, tolerance of the device, and offered further substantiation in this animal model of biocompatibility of the valve and its components.

(6) (b) (2) Clinical testing of the AGV Model S2 was performed at six (6) institutions, to determine the substantial equivalence of the device.

Fifty subjects were recruited for the study. After a pre-operative assessment, subjects were monitored at three immediate and intermediate postoperative periods (up to six weeks), and at additional intervals throughout a six month period.

The subjects, ranging in age from 1 year to 87 years, and consisting of 22 males (44%) and 28 females (56%), were found to have glaucoma of the following etiologies:

	Type of Glaucoma	No. Subjects	Percentages
1.	Neovascular	13	26%
2.	Primary Open Angle	13	26%
3.	Closed-Angle	10	20%
4.	Traumatic	1	2%
5.	Juvenile	3	6%
6.	Infantile	3	6%
7.	Congenital	3	6%
8.	Combined	3	6%
9.	Secondary	1	2%

All fifty patients had a history of uncontrolled high IOP's, averaging 38.52 mmHg. In the immediate post-operative period (4-28 hours), the mean preoperative IOP decreased to 9.66 ± 7.06 mmHg. Hypotony defined as ≤ 5 mmHg was reported in 16 patients. No cases of collapsed chambers were reported.

At the second post-operative reporting period (1-2 weeks), the mean IOP was 10.40 ± 4.5 mmHg. Post-operative complications presented in 20 subjects (40%) at this stage and included mild and moderate iritis (12 cases), mild and moderate corneal edema (8 cases), hypotony (7 cases), hyphema (3 cases), choroidal detachment (3 cases), synechiae (3 subjects) tube/cornea contact (1 case).

At the third exam period (4-6 weeks p.o.), IOPs of 49 patients averaged 14.59 ± 5.43 mmHg. Ten subjects (20.4%) presented with the same complications seen at the 1-2 week reporting period, including three subjects with occlusion of the drainage tube, and one case of exposed scleral graft.

By the third and sixth month reporting periods, (involving 48 subjects), no adverse reactions were reported. The mean post-operative IOP in 48 subjects at six months after surgery was 16.33 ± 4.5 mmHG.

A comparison of results of the sponsor's clinical study of the Ahmed Glaucoma Valve to the Molteno single-plate implant was presented by the sponsor. This confirms the performance of the Ahmed Glaucoma Valve is no worse than the presently marketed device.

(6) (b) (3)
The nonclinical tests described in this Summary demonstrate that the AGV is non-toxic, biocompatible, and physically functional. Another indicator of the safety, and to an extent, the efficacy of the device, was demonstrated by the successful outcome of animal implant experiments.

Additionally, another determination of the success or failure was made six months post-operatively. In the Ahmed valve study, "success" was defined as achievement of a post-operative IOP of 21 mmHg or less, while maintaining or improving visual acuity without the use of glaucoma medications. A "qualified success" was defined as achievement of a post-operative IOP of 21 mmHg or less, while maintaining or improving vision, with the use of glaucoma medications. Any subject having a post-operative IOP of greater than 21 mmHg was considered a "failure".

At six months post-operatively, visual acuity was preserved or improved and IOPs were reduced to 21 mmHg or less and greater than 5 mmHg in 43 of 50 subjects.

The lowering of intraocular pressure achieved with the Ahmed™ Glaucoma Valve is attributed to its physical properties which are similar to other eye valve implants. It creates a channel via the silicone tube for aqueous flow from the anterior chamber to a bleb formed around the encapsulated polypropylene plate. Clinically, intraocular pressure is maintained at an acceptable level in 43 of 50 subjects at six months with this device design.

WARNINGS, PRECAUTIONS

Before using the Ahmed Glaucoma Valve, the implanting surgeon should be skilled in glaucoma filtering procedures and familiar with the use of drainage devices, as well as post-operative care required.

HOW SUPPLIED

The implant is supplied sterile in a sealed peel pouch. Product information and patient chart labels, Implant Notification Card, Patient ID Card are also enclosed with the sterile package. The implant has been terminally sterilized by gamma radiation. Sterility is assured providing the peel pouch has not been opened or damaged, and the sterility expiration date has not lapsed. The peel pouch is intended to be opened using sterile technique, allowing the implant to be dropped into the sterile field.

NOTE: The manufacturer disclaims all warranties expressed or implied, including but not limited to suitability for a particular purpose.

CAUTION: INVESTIGATIONAL DEVICE. LIMITED TO INVESTIGATIONAL USE BY FEDERAL (USA) LAW.

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AHMED™ GLAUCOMA VALVE

MANUFACTURED BY
New World Medical, Inc.

Product Information

DESCRIPTION

The AHMED™ Glaucoma Valve is a valved aqueous humor drainage implant designed to regulate intraocular pressure in eyes suffering from refractory glaucoma. The Ahmed device is comprised of a silicone drainage tube and polypropylene valve/reservoir body which houses a silicone elastomer valve membrane. The valve/reservoir body conforms to the shape of the globe at its equator and protects the valve membrane from blockage by fibrous tissue growth.

INDICATIONS

The Ahmed Glaucoma Valve is indicated for the management of refractory glaucomas, where previous surgical treatment has failed, or by experience is known not to provide satisfactory results. Such refractory glaucomas can include neovascular glaucoma, primary open angle glaucoma unresponsive to medication, congenital or infantile glaucoma, and refractory glaucomas resulting from aphakia or uveitis.

COMPLICATIONS AND ADVERSE REACTIONS

Complications and adverse reactions during or following surgery may include:

Corneal edema	Iritis
Corneal Touch	Hyphema
Synechiae	Tube Obstruction
Choroidal detachment	Exposed scleral graft
Iris tube touch	

as well as known complications of eye valve implants:

Suprachoroidal hemorrhage
retinal detachment

IMPLANT PREPARATION

The implant should be grossly examined and primed for use. Priming is accomplished by injecting balanced salt solution through the drainage tube and valve; insert a syringe with balanced salt solution and a 26-gauge blunt cannula into the open end of the drainage tube and slowly inject approx. 1.0 cc of the solution through the implant. The implant is now ready for use.

GENERAL SURGICAL PROCEDURE

The implant valve body is placed at the superior equator of the globe, between the rectus muscles, in a previously prepared pocket formed by an incision of the conjunctiva and Tenon's capsule and a separation of Tenon's capsule from the sclera. The valve body is sutured to the sclera through the fenestrations on its anterior edge. The drainage tube is trimmed to permit a 2-3 mm insertion of the tube into the anterior chamber. The end should be bevel-cut to an anterior angle of 30 degrees. A limbal-based, two-thirds thickness scleral flap is made. A stab incision under the flap and into the anterior chamber angle is made with a sharp 23-gauge needle. The drainage tube is inserted through the needle track and into the anterior chamber, parallel to iris plane. The scleral flap is closed.

ADDITIONAL INFORMATION

If additional information is required, contact the manufacturer for reprints of articles and papers describing the use of glaucoma implants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

NOV 12 1993

Mr. Robert Fite
President
New World Medical, Inc.
10574 Acacia Street, Suite D-1
Rancho Cucamonga, CA 91730

Re: K925636
Trade Name: Ahmed™ Glaucoma Valve
Implant Model S2
Regulatory Class: III
Dated: August 30, 1993
Received: September 1, 1993

Dear Mr. Fite:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, and 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Interim Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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