

K980657

APR 20 1998

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510(k) SUMMARY

(1) Submitter Information:

New World Medical, Inc.
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Contact Person:

A. Mateen Ahmed, Ph.D.
Date of Summary Preparation: April 9, 1998

(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 Ahmed™ Glaucoma Valve Implant Model S2, as manufactured by New World Medical, Incorporated, and described in their Premarket Notification, K925636. The new Device is Ahmed™ Glaucoma Valve Model S3, K980657.

(4) Device Description

The Ahmed™ Glaucoma Valve (AGV™) is a 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.

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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. This may be generally defined as primary glaucoma, 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™ Model S2 and the AGV™ S3 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, both have a molded silicone water impermeable elastomeric valve membrane. This valve membrane prevents the build-up of excessive intraocular pressure.

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Dimensionally, the following comparisons are tabulated for both the AGV Model S2 and the Ahmed™ Glaucoma Valve (AGV™) Model S3

<u>Valve Implant</u>	<u>Shape</u>	<u>Width (mm)</u>	<u>Length (mm)</u>	<u>Surface (mm)</u>	<u>Height (mm)</u>
Ahmed™ Model S2 Oval Single Plate		13	16	184	1.9
Ahmed™ Model S3 Oval		9.6	10	96	1.9
		<u>Tube Inner Diameter (mm)</u>		<u>Tube Outer Diameter (mm)</u>	
Ahmed™ Model S2 Single Plate		0.317		0.635	
Ahmed™ Model S3		0.317		0.635	

Surgical implantation of the AGV™ Model S2 is essentially identical to that of the AGV™ S3, as is the mechanism of encapsulation of the plate by tissue (bleb formation). After the bleb has been formed, the AGV™ S3 functions in a manner similar to that of AGV™ S2.

(6) (b) (1) 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.

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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:

	<u>Type of Glaucoma</u>	<u>No. Subjects</u>	<u>Percentages</u>
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 15.33 ± 4.5 mmHg.

A comparison of results of the sponsor's clinical study of the Ahmed™ Glaucoma Valve Model S2 to the Ahmed™ Glaucoma Valve Model S3 was presented by the sponsor. This confirms the performance of the Ahmed™ Glaucoma Valve Model S3 is no different than the presently marketed device the Ahmed™ Glaucoma Valve Model S2.

(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.

REFERENCES

- 1 Brown RD, Cairns, JE: Experience with the Molteno long tube implant. *Trans. Oph. Soc. U.K.* 1983; 103: 297-311
- 2 Freedman J: The use of the single stage Molteno long tube seton in treating resistant cases of glaucoma. *Ophthalmic Surgery* 1985; 16: 480-483.
- 3 Hoare Nairne JEA, Sherwood D, et al: Single stage insertior of the Molteno tube for glaucoma and modificatons to reduce postoperative hypotony. *Br J Ophthalmol* 1988; 72: 846-851.
- 4 Lieberman MF, Ewing RH: Drainage implant surgery for refractory glaucoma. *Internaitonal Ophthalmology Clinics* 1990; 30: 198-208.
- 5 Lloyd MA, Sedlak T, Huer DK, et al: Clincial experience with the single-plate Molteno implant in complicated glaucomas. *Ophthalmology* 1992; 99: 679-687.
- 6 Melamed S, Cahane M, Gutman I, Blumenthal M: Postoperative complications after Molteno implant surgery. *Am J Ophthalmol* 1991; 111: 319-322.
- 7 Minckler DS, Heuer DK, Hasty B, et al: Clincial experience with the single-plate Molteno implant in complicated glaucomas. *Ophthalmology* 1988; 95: 1181-1188.
- 8 Molteno ACB, Van Biljon G, Ancker E: Two-stage instertion of glaucoma drainage implants. *Trans Oph Soc New Zealand* 1979; 31: 17-26.
- 9 Molteno ACB, Van Rooyen MMB, Bartholomew RS: Implants for draining neovascular glaucoma. *Br J Ophthalmol* 1977; 61: 120-125.
- 10 Molteno ACB: The optimal design of drainage implants for glaucoma. *Trans. Ophthalmol Soc New Zealand* 1981; 33: 39-41.
11. Molteno ACB, Polkinghorne PJ, Bowbyes JA: The vicryl tie technique for inserting a draining implant in the treatment of secondary glaucoma. *Aust., and NZ J Ophthalmolo* 1986; 14: 343-354.
- 12 Wilson RP, Cantor L, Katz LJ, et al: Aqueous shunts - Molteno versus Schocket. *Ophthalmology* 1992; 99: 672-678.



Food and Drug Administration
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President
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Re: K980657
Trade Name: Ahmed Glaucoma Valve, Model S3
Regulatory Class: Class III
Product Code: KYF
Dated: February 2, 1998
Received: February 5, 1998

Dear Dr. Ahmed:

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) 594-4613. 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" (21 CFR 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/dsmamain.html>".

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980657

Device Name: Ahmed Glaucoma Valve, Model S3

Indications For Use:

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K. Alexander for DRL
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980657

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)