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807.92 510(k) Summary

807.92 a (1)

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Date of Summary Preparation: March 30, 1999

INFORMATION SUBMITTED PURSUANT TO 21 CFR 807.87 (a) - (d)

807.92 (a) (2) Proprietary Name: Ahmed™ Glaucoma Valve Bi-plate

Classification Name: Eye Valve Implant

807.92 (a) (3) An Identification of the legally marketed device to which the submitter claims equivalence.

The predicate device to which Substantial Equivalence is demonstrated is the double plate Molteno Implant, as manufactured by STAAR SURGICAL, Corp., and described in their pre-market notification K875099.

807.92 (a) (4) Description of the device that is the subject of pre-market notification submission.

The Ahmed™ Glaucoma Valve Bi-plate is a modification of an already approved device called the Ahmed™ Glaucoma Valve (AGV™) Ref. 510 (k) 925636 dated November 12, 1993.

The Ahmed™ Glaucoma Valve (AGV™) is an ophthalmic implant for use in intractable Glaucoma.

K 99 1072

CONFIDENTIAL

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 to reduce excessive intraocular pressure by venting aqueous out of the anterior chamber through this control one way valve. The AGV™ implant consists of a silicone drainage tube, a polypropylene valve body to house the valve membrane, and to protect it from occlusion due to fibrosis. All materials used in the manufacturing of this device are of medical grade quality. No metallic or toxic substances are used in the manufacturing of this device. The AGV™ is terminally sterilized by gamma radiation. The AGV™ has a surface area of 184mm². This single plate valve was compared with Molteno Single Plate implant in Pre-market Notification Ref. 510 (k) 925636, and was given approval on November 12, 1993. Since then AGV™ has been very well accepted in the market, and has been proven to be safe and effective.

Some doctors feel that by increasing the surface area would help in ultimate reduction of IOP over longer time periods. This has been demonstrated by Molteno 1981, Brown & Cairns 1983, Molteno 1986, Beebe 1989, Fellman 1989, Lieberman 1990, Llyod 1991, and Heuer 1992. Hence Molteno attached a second plate to the first plate calling it Double Plate Molteno. Molteno, and many other users, such as Brown, Beeb, Fellman, Lieberman, Lloyd, Minckler and others have implanted this Double Plate Molteno since 1981. This device is found to be safe and effective.

The most important clinically significant advantage of using the AGV was reduction in hypotony and complications. In a recently published clinical study by Huan et al "Intermediate-term clinical experience with the Ahmed™ Glaucoma Valve implant." AmJ Ophthal. 1999; 127: 27-33. The results are reported as follows:

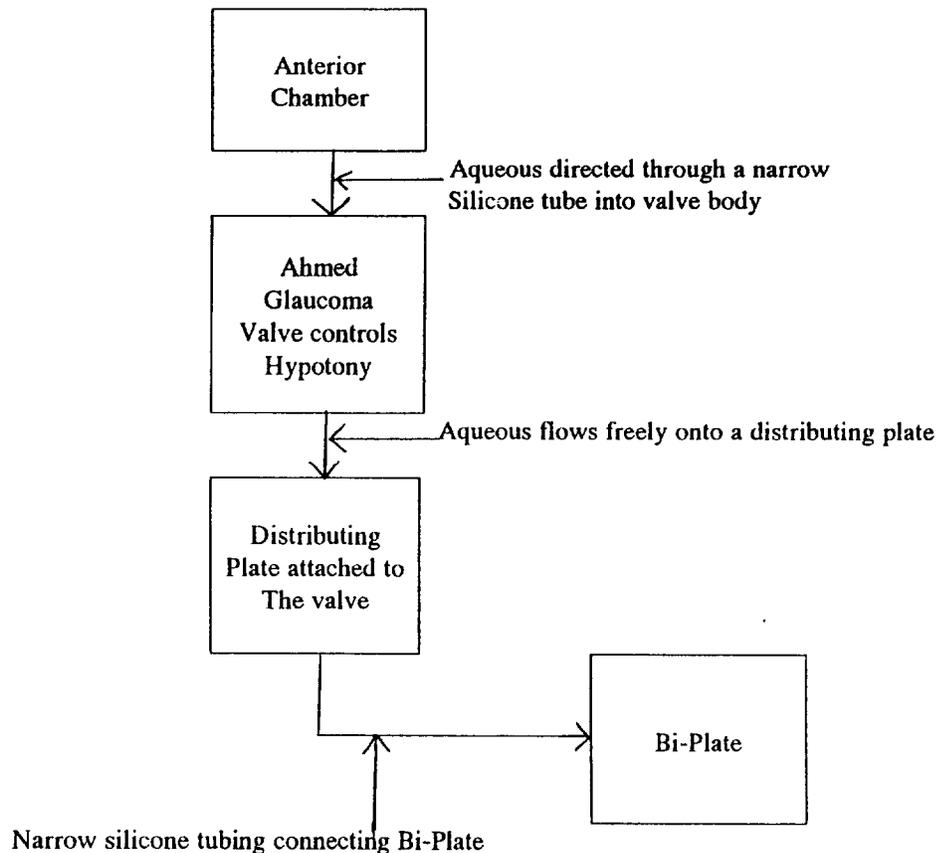
A multi-center, retrospective, clinical follow up of 159 eyes (144 patients) treated with AGV with a mean \pm SEM follow up of 13.4 ± 0.7 months (range 4 to 44 months). The mean SEM age was 60.9 ± 1.9 years (range 0.1 to 103 years). The intraocular pressure was reduced from a mean of 32.7 ± 0.8 mmHg before surgery to 15.9 ± 0.6 mm Hg ($P < .0001$) at the most recent follow-up after surgery. The number of anti-glaucoma medications was decreased from 2.7 ± 0.1 before surgery to 1.1 ± 0.1 after surgery ($P < .0001$). The cumulative probability of success was 87% at 1 year and 75% at 2 years after surgery. The visual acuity was improved or within one snellen tine in 131 eyes (82%). The most common

complication was obstruction of the tube, which was observed in 17 eyes (11%). Transient post-operative hypotony was found in 13 eyes (8%). The above clinical findings indicate that AGV is a safe and effective device. Molteno (1981) compares single plate with double plate in his paper "The optimal Design of Drainage Implants for Glaucoma." Trans. Ophthal.Soc. W.Z. Vol. 33, 1981. Pp. 39-42.

Molteno chose three groups with implant of a single, double and four plates. In the first group with a single plate there were 5 patients having an average age of 72 years. The pre and postoperative pressures ranged from 30.6mm Hg to 25mm Hg without hypertensive medications. In double plate 12 patients were enrolled with a mean age of 75.6 years and mean pre and postoperative pressures of 28.3mm Hg and 12.75mm Hg respectively. The last group had four plates implanted and only three patients were tried with this. The mean age of these patients was 75.3 years and pre and postoperative pressures were 30mm Hg and 10.6mm Hg respectively. The difference between single plate and double plate is highly significant ($P < 0.001$), but between 2 plates and 4 plates is insignificant.

The incidence of early postoperative hypotony differed markedly in three groups; in the case of single plate implants the intraocular pressure was maintained at more than 5mm Hg from the first post operative day in all five cases. With two plate implants the intraocular pressure was likewise wanted at more than 5mm Hg in 11 out of 12 cases. In case of four plate implants however, all three cases showed prolonged hypotony. Molteno also indicates in this paper that it is possible to increase the area of the bleb to 270 mm² without introducing significant postoperative hypotony. In addition he feels that this increase of bleb area resulted in normalization of the intraocular pressure without post hypotensive medication in all the twelve eyes. Molteno goes on to say that the superiority of the double plate design over the single plate has led to its being adopted for routine use in some glaucoma patients though the use of Second plate has not reduced the use of medications to control bleb fibrosis especially in young patients and in severely damaged or inflamed eyes. Molteno concludes that the use of a double plate has helped in reducing post-operative hypotony together with normalization of intraocular pressure without hypotensive medication in 43 out of 52 eyes. Thus use of double plate is safe and effective.

In this application, AGV™ with an attached Bi-plate is being compared with Molteno Double Plate for Substantial Equivalence and to demonstrate that AGV Bi-plate is safe and effective. In case of AGV Bi-plate, the attachment of Bi-plate is provided after the valve, as shown in this flow diagram:



The most important advantage of the AGV™ is to help reduce hypotony. The valve mechanism built into AGV™ has been successful in reducing hypotony and a number of complications that occur due to Hypotony as reported in clinical papers by Anne L. Coleman, 1995, 1996, 1997. Francis 1998, Netland 1998, and Huang 1999.

After implanting the first plate, there is no space in between the rectus muscles. Molteno used other adjoining quadrants to shunt the fluid from the first plate to the second plate, by attaching the second plate to the first by means of a narrow silicone tube. Molteno tried this in 1981, and since then Molteno, Brown, Freedman, Minckler, Heuer, and many others have found this single plate Molteno as well as double plate to be safe and effective.

K991072

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AGV Bi-plate and Molteno Double Plate are substantially equivalent. The same material polypropylene is used in Molteno and Ahmed™. The silicone tubes used are of the same sizes. Ahmed Valve has an extra safety feature to help reduce sudden occurrence of hypotony. This added feature Molteno does not have. The second plate of AGV to the first is attached exactly the same way as in Molteno as well as in AGV. Method of implants of both the devices are exactly the same. Both AGV™ and Molteno have been found to be clinically safe and effective.

Attachment of a second plate to the first after the valve helps to maintain all the advantages of AGV as well as an addition of a second plate will help to increase the surface area. Similar concept was used to Molteno double plate with which substantial equivalence is demonstrated.

807.92 (a) (5) Intended 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 glaucoma resulting from aphakia or uveitis.

807.92 (a) (6) Technological Characteristics

From the stand point 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 eyes anterior chamber to the valve body. The valve body and the body of the second plates both in AGV and Molteno are made of polypropylene. Additionally the AGV has molded silicone water impermeable elastomeric valve membrane. This valve membrane prevents both hypotony, and the build-up of excessive pressure within the anterior chamber. The valve also prevents fluid back flow. Coleman, Francis, Netland, Englet, Molteno, Brown, Freedman, Minckler, and Heuer, and others have reported clinical use of both AGV and Molteno.

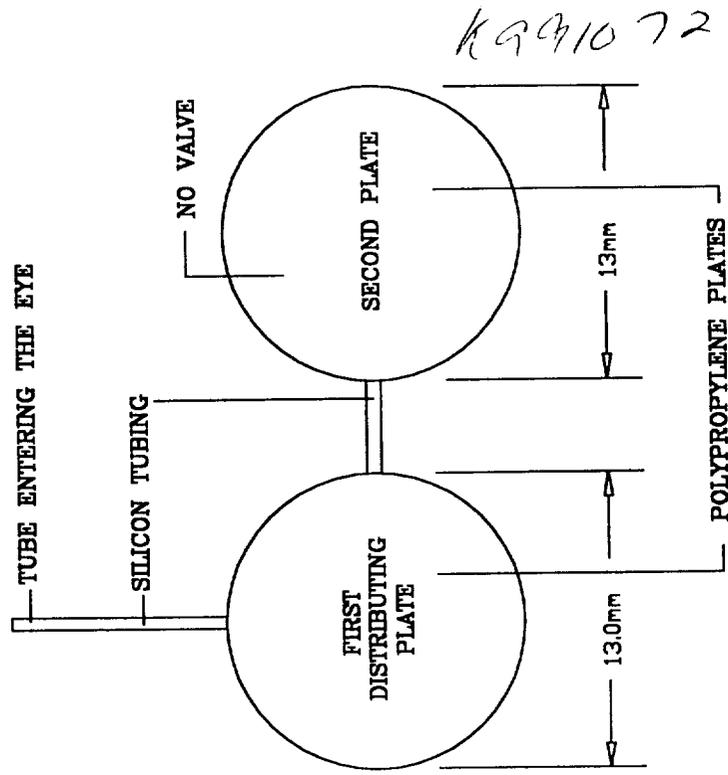
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Dimensionally, the following comparisons are tabulated for both the AGV Bi-Plate and Double Plate Molteno Implants:

Product Parts and Their Dimensions	AGV Bi-Plate	Molteno Double Plate
Shape	Oval	Round
Width in mm	13.0	13.0
Length in mm	16.0	13.0
Surface area in mm ²		
Double Plate In mm ²	360	270
Height in mm	1.9	1.5
Inlet tube Connecting device to Anterior Chamber		
Inner diameter in mm	0.3	0.3
Outer diameter in mm	0.6	0.6
Tube connecting the first plate to Second plate		
Inner diameter in mm	0.3	0.3
Outer diameter in mm	0.6	0.6
Base Plate	Polypropylene	Polypropylene
Second plate	Polypropylene	Polypropylene
Inlet tube from anterior chamber to the valve body	Silicone	Silicone
Tube connecting the two plates	Silicone tube	Silicone tube

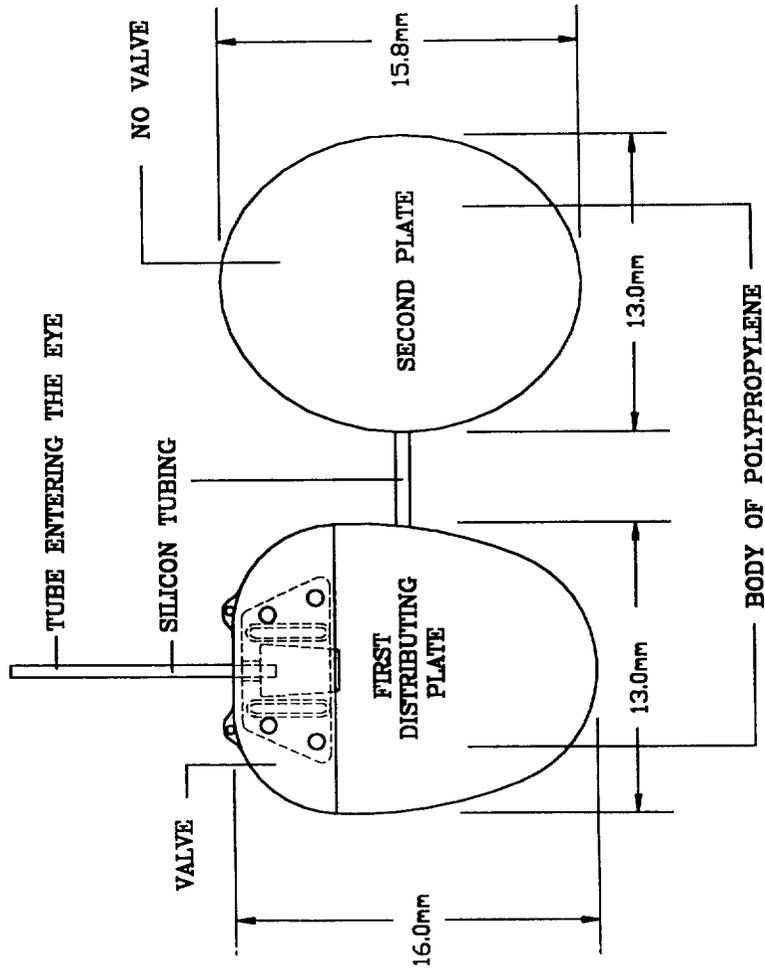
MOLTENO DOUBLE PLATE



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SURFACE AREA 270 sqmm
TUBING:
I.D.: 0.6mm
O.D.: 0.3mm

AHMED GLAUCOMA VALVE
BI-PLATE

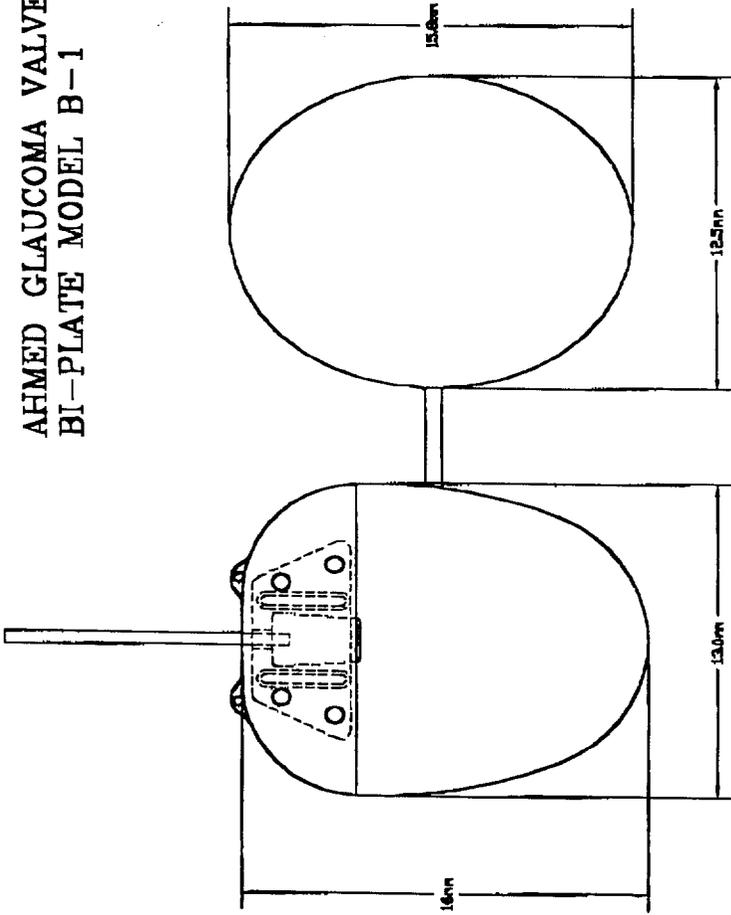


SURFACE AREA 360sqmm
TUBING:
I.D.: 0.3mm
O.D.: 0.6mm

FIG. : SHOWING SUBSTANTIAL EQUIVALANCE

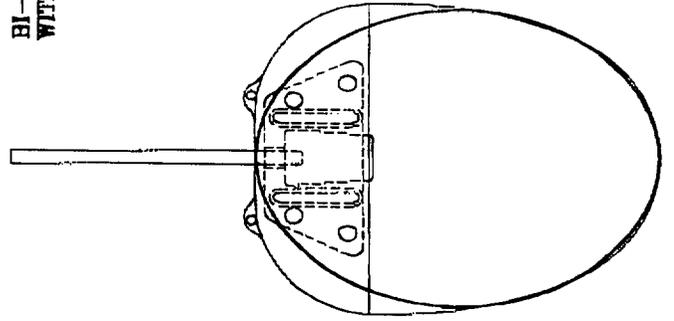
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AHMED GLAUCOMA VALVE
BI-PLATE MODEL B-1



BI-PLATE
WITH NO-VALVE

MAIN VALVE



SUPERIMPOSITION OF BIPLATE
ON THE MAIN VALVE BODY

Surgical implantation of the AGV Bi-plate is essentially identical to that of Double Plate Molteno, as is the mechanism of encapsulation of the plates by tissue (bleb formation). After the bleb is formed, the AGV functions in a similar manner to that of Molteno.

807.92 (6) (b) 1 Non-clinical Testing

Non-clinical testing of AGV encompasses three main types of testing. In vitro laboratory physical testing, in vitro and in vivo biocompatibility testing, and implant studies. Besides from destructive testing no-valve failures were observed in any of the experiments.

All these tests have been explained and reported in 510(k) notification, submitted to FDA on November 6, 1992. An approval of 510(k) was received on the basis of this application on November 12, 1993, Ref. 510(k) K925636.

In vitro laboratory physical testing.

A brief description of this non-clinical test is as follows:

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 AGV was implanted demonstrated its efficacy with regard to control of IOP with the fellow eye used as a control, and tolerance of the device demonstrated further acceptance as in this animal model for biocompatibility of the valve and its components.

807.92 (6) (b) (2)

Clinical testing of the AGV was performed, in 50 patients at five centers for six months as already reported in 510(k) submission K925636 and received approval on November 12, 1993.

Fifty subjects were recruited for the study. After a pre-operative assessment, subjects were monitored at three immediate and intermediate post-operative 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. of subjects	Percentage
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. Comliued	3	6%
9. Secondary	1	2%

All fifty patients had a history of uncontrolled high IOP's, averaging 38.52 mm Hg. In the immediate post-operative period (4-28 hours) the mean pre-operative pressure dropped significantly to 9.66 ± 7.06 mm Hg.

Four cases of hypotonia were reported (but none with collapsed chambers) in the immediate post-operative period, and were attributed to possible iatrogenic causes. All of these resolved within the first few days after surgery.

At the second post-operative reporting period (1-2) weeks), the mean IOP was 10.4 ± 4.5 mm Hg. 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),

three cases of hyphema, three subjects with choroidal detachment, three subjects with synechiae, and one case of tube/cornea contact.

At the third exam period (4-6 weeks post-operative), IOP's of 49 patients averaged 14.59 ± 5.43 mm Hg. Ten subjects (20.4%) presented with the same complications as seen at the 1-2 week reporting period, including three subjects with occlusion of the tube, and one subject with exposed scleral graft. By the third and sixth month reporting periods, (involving 42 and 34 subjects respectively), all post-operative complications had resolved. No adverse reactions were reported. The mean post-operative IOP in 34 subjects at six month after surgery was 16.03 mm Hg. Recently (1999).

807.92 (6) (b) (3)

The non-clinical tests described in this summary demonstrate that the materials used in AGV are all non-toxic, biocompatible, and physically functional. Another feature of the safety and efficacy of the device, was demonstrated by the successful out come of animal implant experiments.

The clinical study of the AGV as described in the previous IDE, and a number of clinical papers ranging from 1995 to 1999 demonstrate both the safety and efficacy of the implant. Addition of another plate of the same material to increase the surface area as done by Molteno and cited in a number of clinical papers Molteno 1981, Brown & Cairns 1983, Molteno 1986, Beebe 1989, Fellman 1989, Lieberman 1990, Lloyd 1991, and Heuer 1992, was proved to be safe and effective. In fact, all studies clearly demonstrate the superiority of AGV over Molteno because of a one way valve system. The data in the clinical study of the AGV, in the treatment of intractable glaucoma demonstrates its effectiveness in prevention of collapse of the anterior chamber during the initial period following implantation (up to approximately six weeks post-operatively). Coleman 1995, 1996, 1997, Francis 1998, Haung 1999, as compared to Molteno implant, and improved maintenance of the IOP within the normal range. By adding a double plate as indicated by Molteno, the safety and effectiveness is in no way compromised.

K991072

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In fact addition of a second plate specially with the AGV helps to increase the surface area of the over all implant, but the control of hypotony of the valve still remains intact, thus making AGV Bi-plate, when compared with an existing device such as Molteno double plate safe and effective.



JUL 13 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

A. M. Ahmed, Ph.D.
President
New World Medical, Inc.
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Rancho Cucamonga, CA 91730

Re: K991072
Trade Name: Ahmed Glaucoma Valve Implant Bi- Plate Model B-1
Regulatory Class: III
Product Code: 86 KYF
Dated: March 30, 1999
Received: March 31, 1999

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 (Pre-market 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.

Page 2 - A. M. Ahmed, Ph.D.

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

