September 8, 2005

PMA Document Mail Center (HFZ-401)
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850

RE: COMPLETED MODULAR PMA: Shell Number M050004/M004
VisionCare Ophthalmic Technologies Implantable Miniature Telescope
IMT(by Dr. Isaac Lipshitz)

Dear Sir or Madam,

Please find enclosed six (6) copies of Module 004 of PMA Shell Number M050004 for the VisionCare Ophthalmic Technologies Implantable Miniature Telescope (IMT). This is the final module for M050004.

VisionCare Ophthalmic Technologies Ltd. is a wholly-owned subsidiary of VisionCare Ophthalmic Technologies, Inc. located at 14395 Saratoga Avenue, Suite 150, Saratoga, California 95070 (the PMA Applicant).

This final module includes the clinical studies performed on the IMT, as well as the summary of safety and effectiveness, financial certification information, and proposed labeling.

The following modules have previously been submitted to FDA for the IMT under M050004:

- M001, dated February 17, 2005. FDA identified two deficiencies in their letter of May 20, 2005, and the Applicant provided an amendment to M001 dated August 10, 2005 that addressed both deficiencies.

- M002, dated August 12, 2005.

- M003, dated June 15, 2005.

Although none of the modules have been formally accepted by FDA, the Applicant is not aware of any outstanding deficiencies for any of the modules.

The information contained in this PMA module and the information that it contains are confidential, and the protection afforded to such confidential information by 18 USC 1905, 21 TJSC 331(I), 5 USC 552, and other applicable laws is hereby claimed.

To facilitate administrative processing of the PMA, a *CDRH Modular Submission Cover Sheet* follows this letter along with a copy of the Medical Device User Fee Cover Sheet. If you have any questions or need any additional information during your review, please contact me at (949) 854-6314 (phone) or (949) 854-9652 (fax).

Sincerely,

Judy F. Gordon, D.V.M.
Regulatory Consultant to VisionCare Ophthalmic Technologies, Inc.

Enclosure

PMA # M050004/M004
VISIONCARE OPHTHALMIC TECHNOLOGIES
IMPLANTABLE MINIATURE TELESCOPE (IMT)

(BY DR. ISAAC LIPSHITZ)

VOLUME I OF IV

SEPTEMBER 8, 2005

APPLICANT

VisionCare Ophthalmic Technologies, Inc.
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VISIONCARE OPHTHALMIC TECHNOLOGIES
IMPLANTABLE MINIATURE TELESCOPE (IMT)
PMA SHELL # M050004/M004

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I. GENERAL INFORMATION

NAME AND ADDRESS OF THE APPLICANT:	VisionCare Ophthalmic Technologies, Inc. 14395 Saratoga Ave., Suite 150 Saratoga, CA 95070 (408) 872-9393 (phone) (408) 872-9395 (fax)
CONTACT PERSON AND OFFICIAL CORRESPONDENT:	Judy F. Gordon, D.V.M. ClinReg Consulting Services, Inc. 2 Delphinus Irvine, CA 92612 (949) 854-6314 (Phone) (949) 854-9652 (Fax)
SIGNATURE OF OFFICIAL CORRESPONDENT:	
DATE OF CONDITIONAL IDE APPROVAL	May 25, 2000
CLASSIFICATION (GENERIC) NAME OF THE DEVICE IF APPLICABLE:	To be determined
TRADE NAME OF DEVICE:	Implantable Miniature Telescope IMT(by Dr. Isaac Lipshitz)
MODEL NUMBERS OF THE DEVICE:	WA IMT 2.2X WA IMT 3.0X
INDICATIONS FOR USE:	The IMT is indicated for use in adult patients with bilateral, stable, untreatable moderate to profound central vision impairment due to macular degeneration.
IDENTIFYING NUMBER OF ALL INDS, NDAS, IDES, PMAS, PDPS, RECLASSIFICATION PETITIONS, OR 510(K)S PREVIOUSLY SUBMITTED FOR THIS DEVICE:	IDE G000115 and related supplements

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NAME AND ADDRESS OF MANUFACTURING & STERILIZATION SITES	Manufacturing Site (new): VisionCare Ophthalmic Technologies, Ltd. 21 Yegia Kapayim Street, Petah Tikva 49001, POB 10133, Israel. Tel: +972 3 928 4000 Fax: +972 3 922 5464 Sterilization Site: Mediplast Israel Ltd. Ha Yarkon St. 7 Yavne, Israel
DATE WHEN MANUFACTURING SITE(S) WILL BE READY FOR INSPECTION OR DATE OF LATEST FDA INSPECTION	The new manufacturing site in Israel for the IMT is being implemented and will be ready for inspection by October 1, 2005
ENVIRONMENTAL IMPACT:	A categorical exclusion to this requirement is claimed under 21 CFR 25.34(g).

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II. EXECUTIVE SUMMARY

VisionCare's Implantable Miniature Telescope (IMT) is a visual prosthetic device which, when combined with the optics of the cornea, constitutes a telephoto lens. The IMT contains two micro lenses that together with the cornea magnify objects in the central visual field, allowing the patient to see without the need of external low-vision aids. A magnified image is projected by the IMT onto the retina, enabling the patient to recognize and identify objects that could not otherwise be seen. The IMT is available in two models: Wide Angle (WA) 2.2X and Wide Angle (WA) 3.0X, which provide nominal magnification of ×2.2 and ×2.7, respectively. The IMT is indicated for use in adult patients with bilateral, stable, untreatable moderate to profound central vision impairment due to macular degeneration.

VisionCare conducted a prospective multicenter clinical trial under IDE G000115, in which a total of 218 consecutive patients were enrolled and 206 patients were implanted at 28 clinical sites and followed over a 24-month period. No patient was allowed to be enrolled in this study without prior written enrollment authorization approval from the Sponsor or its designee.

Effectiveness outcomes exceeded the predefined targets identified in the study protocol. The majority of subjects (approximately 75%) achieved an improvement in best corrected distance acuity of at least 2 lines, with over 60% of eyes gaining 3 or more lines of acuity, 40% gaining 4 or more lines and 20% experiencing a gain of 5 or more lines of distance vision. Similar gains in lines of acuity were achieved for near vision at both 8 and 16 inches. Importantly, these gains in best corrected near and distance acuity were achieved with very little loss of lines of best corrected acuity, as evidenced by the very small number of eyes (n=5) that lost both best corrected distance and near acuity.

With respect to safety, the incidence of complications and adverse events was relatively low and endothelial cell loss is the only parameter that did not meet the pre-specified protocol criterion. While mean endothelial cell loss in the IMT-implanted eyes was greater than the protocol target of 17%, the exhaustive analysis of change in ECD over

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the course of the study presented in this report establishes that the surgical procedure for implantation of the IMT is the single most significant contributor to loss in ECD. This was further confirmed by the stabilization of endothelial cell density between 9 and 12 months.

In this elderly, central vision impaired population suffering from moderate to profound vision loss associated with AMD or Stargardt's macular dystrophy, results of this clinical trial clearly establish the benefit of the clear visual and quality of life benefits following IMT implantation. The magnitude of improvement in vision achieved by the study population supports an acceptable overall risk-to-benefit ratio for the IMT and supports FDA approval of the IMT for patients with vision loss from AMD

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III. DEVICE DESCRIPTION

A general description of the IMT device is provided in the following sections, including background information regarding current treatment modalities for macular degeneration, identification of device components and materials that comprise each component, and a description of the principle of operation and indications for use.

VisionCare's Implantable Miniature Telescope, or IMT is an intraocular visual prosthetic device which, when combined with the optics of the cornea, constitutes a telephoto lens for improvement of visual acuity in patients with moderate to profound visual impairment associated with bilateral end-stage macular degeneration. The IMT is implanted in the posterior chamber of the eye, in place of the eye's crystalline lens and is held in position by haptic loops.

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A. BACKGROUND

Acquired and hereditary macular dystrophies are the leading cause of central vision impairment and blindness. Age related macular degeneration is the most common form of macular dystrophy. Macular degeneration refers to the breakdown of cells in the macula (the center of the retina). Some degeneration is an inevitable consequence of the aging process. However, when it is coupled with the loss of sight in the central part of the field of vision, an underlying pathology is considered present. It is estimated that in the US, macular degeneration affects 1% of all 55-year-olds, and the incidence increases with age, reaching approximately 15% among those aged 80 and over (1). With increasing longevity, it is anticipated that the incidence will increase significantly (1).

The main effect of macular degeneration is to reduce the ability of the individual to engage in everyday activities that require high resolution vision. It is associated with elevated risk of depression, increased levels of dependency, and an overall decrease in the quality of life (2-4).

Currently there is no effective treatment for the majority of patients. For a minority of patients, (i.e., those with wet macular degeneration resulting from choroidal neovascularization (CNV), advances in new therapies have led to improvements in the management of the rate of vision loss. Treatments include photodynamic, biopharmaceuticals, submacular surgery and photoablation. However, no viable treatments are available for the several hundred thousand individuals with moderate to severe central vision loss due to late stage dry, atrophic macular degeneration, end stage CNV with disciform scar and other maculopathies such as Stargardt's macular dystrophy.

The only corrective interventions currently available for these patients are low vision aids such as special spectacles and head-mounted or hand-held telescopes, which magnify images onto the retina. These aids are widely available but have only limited patient acceptance. Patients find these aids bulky, uncomfortable and unattractive. In addition, use of external telescopes requires suppression of natural eye movements. Instead, the patient must learn to scan the visual field by moving his/her entire head. If not properly

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adapted to this requirement for behavioral change, a conflict between the visual and vestibular systems will arise, resulting in nausea.

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B. GENERAL DESCRIPTION

VisionCare's Implantable Miniature Telescope, or IMT is a visual prosthetic device which, when combined with the optics of the cornea, constitutes a telephoto lens for improvement of visual acuity in patients with bilateral macular degeneration. The IMT is implanted in the posterior chamber of the eye, in place of the eye's crystalline lens and is held in position by haptic loops.

A picture of the IMT is provided below in Figure 1. The device contains two micro lenses, which magnify objects in the visual field, allowing the patient to see without the need for external low-vision aids. A magnified image is projected by the IMT onto the retina, enabling the patient to recognize and identify objects that could not otherwise be seen. The IMT is available in two models: Wide Angle (WA) 2.2X, and Wide Angle (WA) 3.0X, which provide nominal magnification of ×2.2 and ×2.7, respectively.

Both models are designed predominantly for the restoration of intermediate-far vision (increasing the ability to view objects several meters away from the patient). The addition of conventional spectacles provides correction for near vision activities.

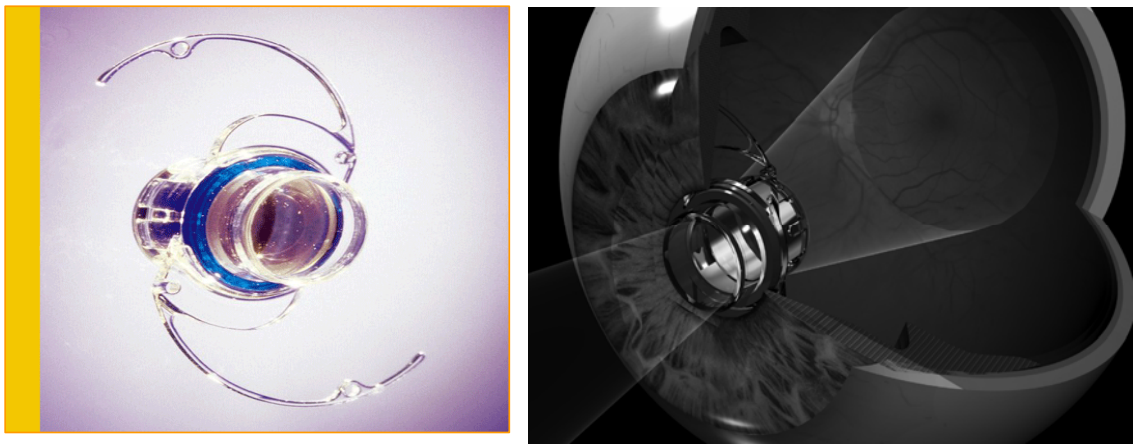

FIGURE 1: PICTURES OF A WA IMT

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The IMT is implanted in one eye of a patient. The implanted eye provides central vision, while the fellow eye continues to be used for peripheral vision.

The IMT is composed of three primary components; a fused silica capsule that contains optical elements, a clear polymethyl methacrylate (PMMA) carrier, and a blue PMMA light restrictor. The optical component is snap-fitted into the carrier. All materials are biocompatible for long-term ocular implantation per ISO 10993. One of the internal components (not in contact with body fluids or tissue) of the IMT contains stainless steel, which may interfere with the safe use of Magnetic Resonance Imaging (MRI). Until MRI compatibility of the IMT has been established, the use of MRI is contraindicated. The IMT is assembled and packaged in a controlled environment and is sterilized by ethylene oxide. Table 3-1 below compares the finished product specifications of the two device models. Engineering drawings for both models are provided in Attachment B.1.

Each IMT is packaged in a protective polycarbonate case with cap, which assures that the device is held firmly during handling and transportation. The case with IMT is placed in a Polyethylene (PETG) blister, which is sealed with a Tyvek® lid. Following ethylene oxide sterilization, the blister is placed in a unit box with labels and product information. The expiration date appears on the outside of the Tyvek® lid and on the outside of the box (the shelf-life is 2-years from the date of manufacture).

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TABLE 3-1
FINISHED PRODUCT SPECIFICATIONS OF THE IMT MODELS INSIDE THE EYE

FEATURE	MODEL WA 2.2X	MODEL WA 3.0X
MAGNIFICATION	x 2.2 ± 10%	x 2.7 ± 10%
DEPTH OF FIELD	1.5 to 10 m	1.5 to 10 m
OPTIMAL FOCUSING DISTANCE	3 m	3 m
FIELD OF VIEW	Full field: 24º (Nominal), 52.8º on the retina Center (High Resolution): 9º, 20º on the retina	Full field: 20º (Nominal), 54º on the retina Center (High Resolution): 6º, 16.2º on the retina
OPTICAL TRANSMISSION (VISIBLE SPECTRUM)	T > 80% in the eye T > 70% in air	T > 80% in the eye T > 70% in air
DIMENSIONS		
Overall Diameter	13.5 mm	13.5 mm
Clear Aperture	3.2 mm	3.2 mm
Telescope Diameter	3.6 mm	3.6 mm
Axial Length	4.4 mm	4.4 mm
Haptic Angulation	12.7°	12.7°
WEIGHT		
Air	115 mg ± 10%	115 mg ± 10%
Aqueous	60 mg ± 10%	60 mg ± 10%

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ATTACHMENT B.1

IMT ENGINEERING DRAWINGS

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C. DEVICE COMPONENTS

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C.1 TELESCOPE

The telescope, also referred to as the capsule or telescope capsule in various documents, is comprised of a glass tube in which the optics are located. The optics are assembled from the following components that were identified above in Table 3-2: Front Lens, Back Lens, Bushing, and Loctite 3492 glue. This assembled optical component is referred to as a "doublet lens". The doublet lens is glued within the tube/distal window assembly with Loctite 5088. The anterior (front) window is then welded onto the assembly. The windows are made of Synthetic Fused Silica, Heraeus Suprasil 300.

The central Field of View (FOV) of the IMT provides sufficient image resolution for different tasks such as reading, face recognition and TV watching at graded visual fields of up to maximum of 9º (20º on the retina) for the wide angle Model WA 2.2X and 6º (16.2º on the retina) for the wide angle Model WA 3.0X.

The wide angle IMT nominal FOV provides detection abilities at a visual angle of 20º (54º on the retina) for the Model WA 3.0X and 24º (52.8º on the retina) for the Model WA 2.2X.

C.2 CARRIER & HAPTICS

For both device models, the telescope is snap fit into a one-piece, transparent, medical grade PMMA carrier with haptics. This carrier/loop component is what supports the device within the eye. The haptics range in thickness from 0.18 mm – 0.20 mm and are positioned at a 12.7º angulation from planar. The carrier has two sets of positioning holes, one set on the carrier body and another on the loops.

C.3 LIGHT RESTRICTOR

A blue PMMA light restrictor is placed on the anterior surface of the carrier in order to reduce the amount of light penetration around the device optic to the retina.

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D. PRINCIPLE OF OPERATION

The IMT provides improved near or distance vision correction in the same fashion as an external telescope (Figure 2). The device is implanted in the capsular bag in the posterior chamber of the eye, in place of the eye's crystalline lens. It is held in position by haptic loops using a surgical procedure similar to that used in earlier era large incision refractive cataract surgery.

The IMT is indicated for use in adult patients with bilateral, stable, untreatable moderate to profound central vision impairment due to macular degeneration. Vision loss must be sufficiently advanced to have caused significant or complete loss of normal central vision, but adequate peripheral vision must be retained. The IMT is only implanted in one of the patient's eyes. In this way, the implanted eye provides central vision and the non-implanted eye provides peripheral vision.

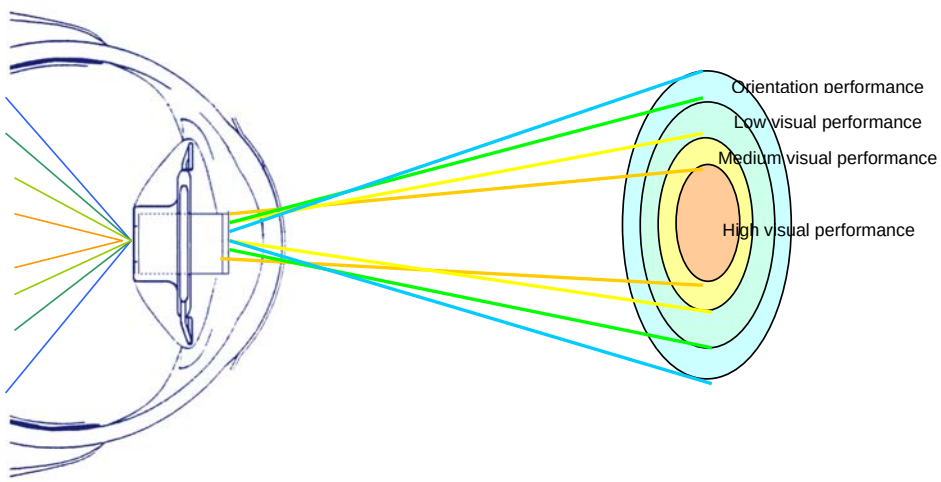

FIGURE 2. ILLUSTRATION OF IMAGE QUALITY DISTRIBUTION WITH THE IMT

The primary advantage of the IMT over alternative treatments for low vision is that the IMT allows scanning of reading materials and other images using natural eye

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movements, rather than head movements. Since there is no relative movement between the eye and the telescope, the image quality is stable in all directions of sight. The placement of the magnifying device entirely inside the eye eliminates increased speed of motion and vestibular conflict.

If there is further deterioration of the macula after the implantation, the amount of magnification for viewing close objects (reading) can be increased by bringing the object closer to the eye by adding low-plus eyeglasses (+1.00 to +3.2 D). With glasses, up to 8X relative magnification can be achieved at 18 cm with the wide angle Model WA 3.0X (relative to the normal eye at the standard reading distance of 40 cm).

Patients will be given the opportunity to choose which type of visual restoration is more meaningful in their lives by wearing the different corresponding external telescopes for a proper period of acclimation before selecting the IMT that is likely to provide the preferred vision enhancement.

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E. INDICATIONS FOR USE

The IMT is indicated for use in adult patients with bilateral, stable, untreatable moderate to profound central vision impairment due to macular degeneration.

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IV. DECLARATION OF CONFORMANCE TO STANDARDS AND REGULATIONS

The clinical investigation performed on the IMT and the results presented in this PMA module conform to the relevant sections of the following current standards and regulations.

NUMBER	STANDARD TITLE
ISO 11979-7	Ophthalmic Implants – Intraocular Lenses; Part 7 – Clinical Investigations
ISO 14155-1	Clinical Investigation Of Medical Devices Of Human Subjects - Part1: General Requirements
ISO 14155-2	Clinical Investigation Of Medical Devices For Human Subjects - Part 2: Clinical Investigation Plans
21 CFR Part 812	Investigational Device Exemptions
21 CFR Part 50	Protection of Human Subjects
21 CFR Part 54	Financial Disclosure by Clinical Investigators
21 CFR Part 56	Institutional Review Boards

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V. ENVIRONMENTAL ASSESSMENT

VisionCare Ophthalmic Technologies, Inc. hereby claims a categorical exclusion from the requirement to prepare an Environmental Assessment for the IMT in accordance with 21 CFR 25.34(d). The proposed action, approval of the PMA, qualifies for categorical exclusion as the IMT device is similar enough in type and use to previously approved intraocular lenses. No extraordinary circumstances exist that would significantly affect the quality of the human environment as a result of the proposed action.

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VI. SUMMARY OF SAFETY AND EFFECTIVENESS DATA

In accordance with 21 CRF Part 814.20(b)(3)(v), enclosed please find on the following pages a summary of safety and effectiveness data for the IMT device.

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VII. DEVICE LABELING

In accordance with 21 CRF Part 814.20(b)(10), enclosed please find copies of all proposed labeling in the following sections:

A. Professional Use Information

B. Patient Information Booklet

C. Package Labeling

D. Surgeon Training

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A. PROFESSIONAL USE INFORMATION

A draft of the Professional Use Information booklet is provided on the following pages.

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B. PATIENT INFORMATION BOOKLET

A draft of the Patient Information booklet is provided on the following pages.

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C. PACKAGE LABELS

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D. SURGEON TRAINING

To ensure the safe and effective use of the Implantable Miniature Telescope, VisionCare proposes implementation of a training program for ophthalmic surgeons who wish to use the device. VisionCare will provide a comprehensive training program for surgeons who are experienced in the medical management and surgical procedures of the anterior segment. The training program will include information on patient selection, surgical technique and postoperative management of patients implanted with the IMT.

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VIII. FINANCIAL CERTIFICATION / DISCLOSURE

In accordance with 21 CFR Part 54, a completed financial certification Form FDA 3454 is provided in Attachment A. Since no investigators were reported with any financial interest in VisionCare Ophthalmic Technologies, Inc. or VisionCare Ophthalmic Technologies, Ltd., a financial disclosure Form FDA 3455 is not required.

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ATTACHMENT A

IMT CLINICAL INVESTIGATION

FINANCIAL CERTIFICATION FORM FDA 3454

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IX. CLINICAL REPORT

A clinical investigation of the IMT was performed in the U.S. under IDE G000115, and a copy of the clinical report for this study is provided on the following pages. The purpose of this clinical report is to describe the safety and effectiveness of IMT implantation in patients with dry AMD, in support of this marketing application (PMA) for the IMT.

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X. BIBLIOGRAPHY FOR MODULE 4

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