ASX RELEASE
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FDA Clears iTrack™ Advance for U.S. Launch

- **New *iTrack™ Advance* will appeal to a substantially larger new market.**
- **U.S. launch planned for the American Society of Cataract and Refractive Surgery (ASCRS) conference in San Diego May 5-8, 2023.**

Nova Eye Medical Limited (ASX: **EYE**) (**Nova Eye** or the **Company**), confirms that U.S. Food and Drug Administration (FDA) has cleared the Company's newest generation canaloplasty device for canal-based glaucoma surgery, the iTrack™ *Advance*, for sale to surgeons in the USA to treat glaucoma.

The original *iTrack*™ was the pioneering canaloplasty device that first established canal surgery for glaucoma and to date approximately 120,000 surgeries have been performed by surgeons worldwide with outstanding clinical efficacy and safety profile. The *iTrack*™ microcatheter is the only product that is indicated for canal surgery to treat glaucoma with viscodilation alone.

iTrack™ *Advance* is the latest addition to the iTrack™ family and is a high precision hand-held delivery system that places the clinically proven iTrack™ microcatheter into the main drainage canal of the eye for injection of viscoelastic fluid (canaloplasty) to clear blockages that cause elevated eye pressure (glaucoma). The original iTrack™ is principally used by glaucoma surgeons whereas the new iTrack™ *Advance*, with the extended feature set, is expected to appeal to glaucoma surgeons as well as cataract surgeons and comprehensive surgeons, for use in a combination procedure alongside cataract surgery. *iTrack*™ *Advance* can be used by surgeons for both standalone procedures as well as in combination with cataract surgery.

With FDA 510(k) clearance secured, Nova Eye can immediately commence marketing and sales of *iTrack*™ *Advance* to U.S. ophthalmologists for the treatment of glaucoma. A full product launch is planned for the American Society of Cataract and Refractive Surgery (ASCRS) annual conference scheduled for May 5-8, 2023 in San Diego.

Commenting on the FDA clearance, Nova Eye Medical Managing Director, Tom Spurling, said:

> ***"Having pioneered canaloplasty technology with the original iTrack™ device, Nova Eye is now well positioned to materially penetrate the expanding canal surgery market with iTrack™ Advance."***

According to Mahmoud A. Khaimi, Clinical Professor, James P. Luton, MD Endowed Chair in Ophthalmology at the Dean McGee Eye Institute, University of Oklahoma, the introduction of the new *iTrack™ Advance* will make the canaloplasty procedure much more accessible to the broader market of cataract and anterior segment surgeons.

> *"I've been given the great opportunity and honour to pair hand in hand with Nova Eye to develop the iTrack™ Advance. We've taken the original iTrack™ device and incorporated it into an ergonomic handpiece that allows surgeons to easily advance and retract the microcatheter through the canal.*
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> *With this new design we have streamlined the canaloplasty procedure and made it efficient and very ergonomic for the surgeon. I am confident that surgeons will adopt this device into their treatment algorithm, either as an adjunct to cataract surgery or as a standalone procedure," said Dr. Khaimi.*

For more information about *iTrack™ Advance*, including important safety information, visit: itrack-advance.com

For additional information about Nova Eye Medical and its technologies, visit: nova-eye.com

Authorised for lodgement to ASX by the Board of Directors of Nova Eye Medical Limited

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ABOUT NOVA EYE MEDICAL LIMITED

Nova Eye Medical Limited is a medical technology company that develops, manufactures and sells a portfolio of proprietary ophthalmic treatment technologies and devices. Used by eye surgeons in globally, these technologies include iTrack™ minimally invasive glaucoma surgery (MIGS), a consumable surgical device that restores the eye's natural outflow pathway to lower pressure inside the eye and to eliminate patient reliance on anti-glaucoma medications for mild-moderate glaucoma. The Molteno3® glaucoma drainage device platform is designed to enhance surgical utility and optimize clinical outcomes for long term IOP control in cases of severe glaucoma. With its sales headquarters based in Fremont, California, Nova Eye Medical is supported by a global network of distribution partners. Manufacturing facilities are located in Fremont, California and Dunedin, New Zealand.