March 30, 2023

Nova Eye Inc. (Business name Nova Eye Medical)
% Evelyn De La Vega Stewart
Consultant
EDS Regulatory Consulting Inc.
95 Bryce Run
Lake Forest, California 92630

Re: K221872
Trade/Device Name: iTrack™ Advance Canaloplasty Microcatheter with Advanced Delivery System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: MPA, HMX
Dated: February 27, 2023
Received: March 1, 2023

Dear Ms. Evelyn De La Vega Stewart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bennett N. Walker -S

Digitally signed by Bennett N. Walker -S
Date: 2023.03.30 10:20:42 -04'00'

For Tieuvi Nguyen, Ph.D.
Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221872

Device Name
iTrack™ Advance Canaloplasty Microcatheter with Advanced Delivery System

Indications for Use *(Describe)*
The Nova Eye iTrack™ Advance is indicated for fluid infusion or aspiration during surgery.

The Nova Eye iTrack™ Advance is indicated for catheterization and viscodilation of Schlemm's Canal to reduce intraocular pressure in adults patients with open-angle glaucoma.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

October 21, 2022

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92

Submitter Information:

510(k) Owner Name: Nova Eye Medical
41316 Christy Street
Fremont, CA 94538
1-800-391-2316

Contact: Don Watton
Head of Global Operations
Nova Eye Medical
1-800-391-2316

Device Name and Classification:

Trade/Proprietary Name:	**iTrack™ Advance - Canaloplasty Microcatheter with Advanced Delivery System**	
Device Common Name:	**Ophthalmic Microcatheter**	
Model Number	**iTrack™ ADS**	
Classification Names:	Endoscope and accessories	Manual ophthalmic surgical instrument, cannula
Regulations:	21 CFR 876.1500	21 CFR 886.4350
Classification	Class II	Class I
Product Codes:	MPA	HMX

Predicate Device:

Device Name:	**510(k) Number**
Nova Eye Inc, Canaloplasty Microcatheter iTrack™ 250A	K080067 (Predicate)

Intended Use:

The iTrack™ Advance is intended for the delivery of controlled amounts of viscoelastic fluid during ophthalmic surgery, and for the microcatheterization and viscodilation of Schlemm's Canal (Canaloplasty) to reduce intraocular pressure.

Indications for Use:

The Nova Eye iTrack™ Advance is indicated for fluid infusion or aspiration during surgery.

The Nova Eye iTrack™ Advance is indicated for catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open-angle glaucoma.

Device Description:

The iTrack™ Advance is a sterile, single-use manual handheld ophthalmic instrument used by ophthalmologists for infusion and aspiration of fluids during ophthalmic surgery and for catheterization and viscodilation of the Schlemm's canal (Canaloplasty) to reduce intraocular pressure in adults with open-angle glaucoma. After catheterization and viscodilation of the entire circumference of Schlemm's canal, the device may also be used to place a tensioning suture within the canal.

The iTrack™ Advance has a handpiece preloaded with an illuminated and flexible microcatheter. The addition of the handpiece provides for improved ergonomics and user interface by allowing single handed delivery of the microcatheter into the eye. The actuator on the handpiece is pushed forward slowly and this advances the catheter around the Schlemm's canal the full 360 degrees. By then sliding the actuator on the handpiece back the catheter is withdrawn back into the handpiece and as this takes place the viscoelastic is injected into the canal using the Ophthalmic ViscoInjector.

The iTrack™ Advance is manufactured from biocompatible materials, common within the medical device industry, such as stainless steel, nitinol, and thermoplastics such as polycarbonate, Pebax®, and polymethyl methacrylate (PMMA). The device includes a stainless-steel cannula, a composite microcatheter, and a polymeric manual handpiece.

Additionally, the device is used with a single use manually operated infusion pump (the Ophthalmic ViscoInjector™) and the iLumin™ Fiberoptic Illuminator console (cleared separately in K050716 and K062259 and as a kit in iTrack™ 510(k) K080067).

Figure 5-1: iTrack™ Advance - Canaloplasty Microcatheter with Advanced Delivery System

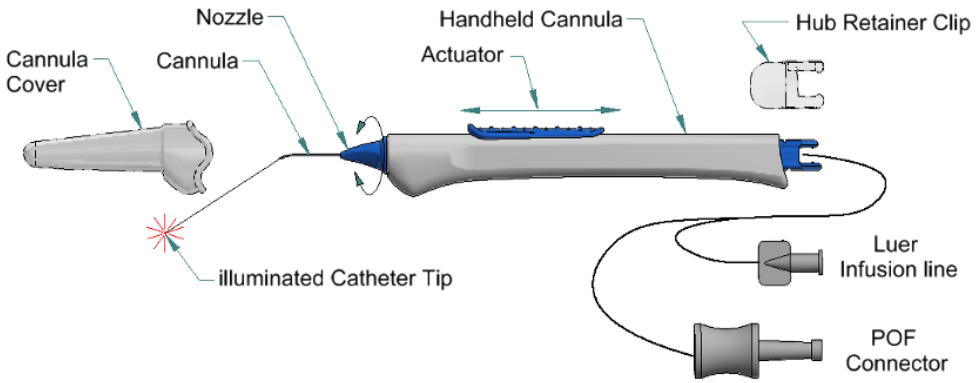
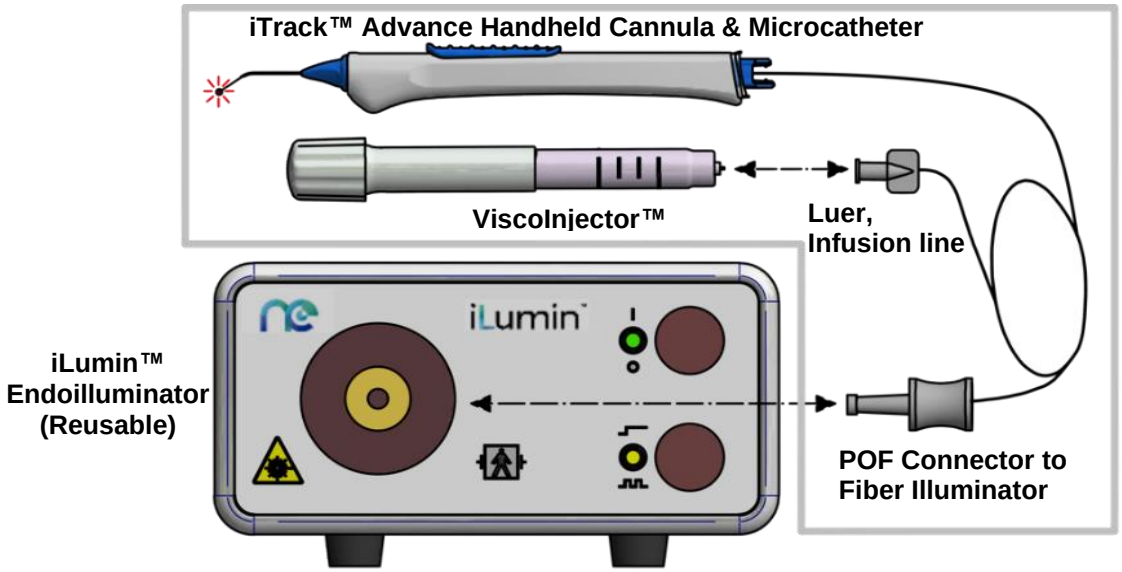


Figure 5-2: Schematic of the iTrack™ Advance with iLumin™ Endoilluminator



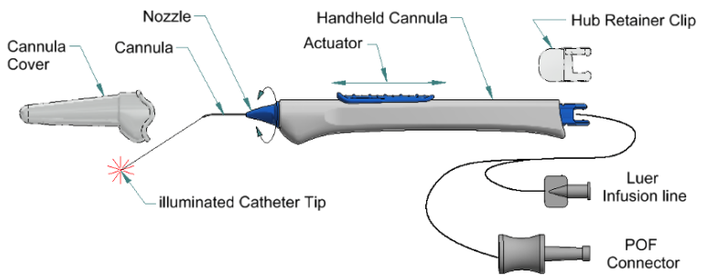
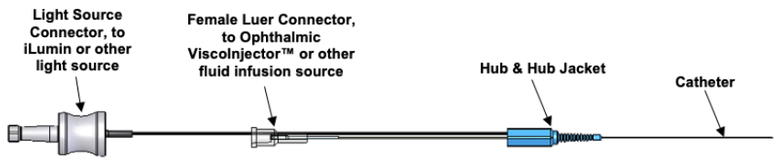
Technological Characteristics (in comparison to predicate):

The technical features of the subject device (iTrack™ Advance) compared to the predicate device (iTrack™ 250A) are substantially equivalent. The iTrack™ Advance microcatheter retains the same materials, design, and accessories as the predicate, and comprises a handpiece to allow manipulation of the catheter without the need for surgical forceps when performing canaloplasty. Both the predicate and subject devices maintain the same indications for use and intended use. Both are manually operated devices that are intended for catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open-angle glaucoma (canaloplasty).

The subject and predicate device maintain the same manual principle of operation and engage the use of an ergonomic handpiece to assist in the delivery of viscoelastic in target intraocular spaces.

The following table compares the characteristics of the iTrack™ Advance with the predicate device iTrack™ 250A (K080067). See Table 5-1.

TABLE 5-1 DEVICE TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE

Characteristic	**Nova Eye Canaloplasty Microcatheter with Advanced Delivery System - iTrack™ Advance (K221872)** **SUBJECT DEVICE**	**Nova Eye Canaloplasty Microcatheter -iTrack™ 250A (K080067)** **PRIMARY PREDICATE**
Device		
Intended Use	Delivery of controlled amounts of viscoelastic fluid during ophthalmic surgery, fluid infusion and aspiration, and catheterization and viscodilation (canaloplasty) to reduce intraocular pressure.	Delivery of controlled amounts of viscoelastic fluid during ophthalmic surgery, fluid infusion and aspiration, and catheterization and viscodilation (canaloplasty) to reduce intraocular pressure.
Indications for Use	The Nova Eye iTrack™ Advance Canaloplasty Microcatheter is indicated for fluid infusion or aspiration during surgery. The Nova Eye iTrack™ Advance Canaloplasty Microcatheter is indicated for catheterization and viscodilation of Schlemm's canal (canaloplasty) to reduce intraocular pressure in adult patients with open-angle glaucoma.	The Nova Eye iTrack™ Advance Canaloplasty Microcatheter is indicated for fluid infusion or aspiration during surgery. The Nova Eye iTrack™ Canaloplasty Microcatheter is indicated for catheterization and viscodilation of Schlemm's canal (canaloplasty) to reduce intraocular pressure in adult patients with open-angle glaucoma.

Characteristic	**Nova Eye Canaloplasty Microcatheter with Advanced Delivery System - iTrack™ Advance (K221872)** **SUBJECT DEVICE**	**Nova Eye Canaloplasty Microcatheter -iTrack™ 250A (K080067)** **PRIMARY PREDICATE**
Regulation	876.1500 (Endoscope and accessories) 886.4350 (Manual ophthalmic surgical instrument)	876.1500 (Endoscope and accessories) 886.4350 (Manual ophthalmic surgical instrument)
Device Class	Class II	Class II
Product Code	MPA (Endoscope) HMX (Manual Ophthalmic Surgical Instrument)	MPA (Endoscope) HMX (Manual Ophthalmic Surgical Instrument)
Prescription Status	Prescription use only	Prescription use only
Target Anatomy	Schlemm's Canal	Schlemm's Canal
Accessories	For use as part of a system/kit including: Manual Accessory: Ophthalmic ViscoInjector™ (K050716) Powered Accessory: iLumin™ Fiberoptic Illuminator (K062259).	For use as part of a system /kit including: Manual Accessory: Ophthalmic ViscoInjector™ (K050716) Powered Accessory: iLumin™ Fiberoptic Illuminator (K062259).
Viscoelastic	Viscoelastic is supplied separately from unaffiliated manufacturers. Viscoelastic is delivered to/attaches to device via luer fitting.	Viscoelastic is supplied separately from unaffiliated manufacturers. Viscoelastic is delivered to/attaches to device via luer fitting.
Dispensing control	Manual rotation of ViscoInjector™ knob to dispense controlled amounts viscoelastic fluid	Manual rotation of ViscoInjector™ knob to dispense controlled amounts viscoelastic fluid
User determines amount of fluid to dispense	Yes, by rotating the proximal knob on the ViscoInjector™	Yes, by rotating the proximal knob on the ViscoInjector™
Passive or Energized Device to Dispense Viscoelastic	Passive	Passive
Volume Dispensed	2.25µL per click of the VI	2.25µL per click of the VI
Dispensing Mechanism	Syringe volume exchange	Syringe volume exchange

Characteristic	**Nova Eye Canaloplasty Microcatheter with Advanced Delivery System - iTrack™ Advance (K221872)** **SUBJECT DEVICE**	**Nova Eye Canaloplasty Microcatheter -iTrack™ 250A (K080067)** **PRIMARY PREDICATE**
Operating Principle	Manual	Manual
Mechanism Of Action	**Ophthalmic Microcatheter and Handheld Ophthalmic Cannula** **Mechanism of action** • The Microcatheter is connected to the ViscoInjector™ and primed with viscoelastic fluid from a cartridge retained with the ViscoInjector. • The Microcatheter is connected to a powered iLumin™ Fiberoptic Illuminator which illuminates the Microcatheter tip. • The surgeon holds the handheld ophthalmic cannula like a pen and aligns the catheter into the scleral dissection and into the ostium of the Schlemm's canal. • The surgeon advances the microcatheter inside the ostium of the Schlemm's canal by sliding forward the manually controlled actuator on the handheld ophthalmic cannula. • The Microcatheter can access 360° of the Schlemm’s canal in one pass. • The surgeon withdraws the microcatheter from the Schlemm’s canal by sliding the manually controlled actuator on the handheld ophthalmic cannula. • As the microcatheter is withdrawn from the Schlemm’s canal, viscoelastic fluid is delivered into canal space by manual clockwise rotation of the knob on the ViscoInjector • Clicks on the ViscoInjector™ tactilely indicate precise delivery of viscoelastic fluid.	**Ophthalmic Microcatheter** **Mechanism of action** • The Microcatheter is connected to the ViscoInjector™ and primed with viscoelastic fluid from a cartridge retained with the ViscoInjector. • The Microcatheter is connected to a powered iLumin™ Fiberoptic Illuminator which illuminates the Microcatheter tip. • The surgeon directs the microcatheter using micro forceps through the surgical incision into the ostium of the Schlemm's canal. • The Microcatheter can access 360° of the Schlemm’s canal in one pass. • As surgeon withdraws the microcatheter from the Schlemm’s canal, viscoelastic fluid is delivered into the canal by the surgeon by manual clockwise rotation of the knob on ViscoInjector. • Clicks on the ViscoInjector™ tactilely indicate precise delivery of viscoelastic fluid.
Materials	Medical grade materials including: Polyimide, Polycarbonate, Pebax, Stainless Steel, Polystyrene, PMMA, PVDF, Polypropylene, Polyketone, Nitinol	Medical grade materials including: Polyimide, Polycarbonate, Pebax, Stainless Steel, Polystyrene, PMMA, PVDF

Characteristic	**Nova Eye Canaloplasty Microcatheter with Advanced Delivery System - iTrack™ Advance (K221872)** **SUBJECT DEVICE**	**Nova Eye Canaloplasty Microcatheter -iTrack™ 250A (K080067)** **PRIMARY PREDICATE**
User Interface	Handheld	Handheld
Microcatheter Shaft Outer Diameter	200 microns	200 microns
Microcatheter Tip Outer Diameter Range	0.0098 inches	0.0098 inches
Length of microcatheter available for surgery	45mm	45mm
Sterile and Single Use	Provided sterile. Single patient use	Provided sterile. Single patient use
Sterilization Method	Gamma radiation	Gamma radiation
Sterility Assurance Level	10^{-6}	10^{-6}
Packaging	Closed tray inside a sealed Tyvek pouch	Closed tray inside a sealed Tyvek pouch
Shelf Life	2 years	2 years

Performance Testing

The device was subjected to testing to support and demonstrate substantial equivalence to the predicate device. The testing was performed as follows:

Functional Performance and Safety Testing

- Biocompatibility testing was completed per
  - *ISO 10993-1 Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process*
  - *21 CFR 58 Good Laboratory Practice for Nonclinical Laboratory Studies*.
  - Cytotoxicity as per the requirements established in *ISO 10993-5, Biological Evaluation of Medical Devices -- Part 5, Tests for in vitro cytotoxicity*.
  - Irritation and Sensitization as per the requirements established in *10993-10, Biological Evaluation of Medical Devices -- Part 10: Tests for Irritation and Skin Sensitization.*
- Sterilization testing was completed per
  - *ANSI/AAMI/ISO 11737-1:2018 Sterilization of health care products- Microbiological methods -Part 1: Determination of the population of microorganisms on product,*
  - *ANSI/AAMI/ISO 11737-2 Sterilization of medical devices -Microbiological methods-Part 2: Tests of sterility performed in the definition, validation and maintenance of sterilization process,*
  - *ANSI/AAMI/ISO 11137-1 Sterilization of health care products -Radiation -Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* and
  - *ANSI/AAMI/ISO 11137-2 Sterilization of health care products- Radiations -Part 2: Establishing the sterilization dose.*
    - The device maintains a sterility assurance level of SAL $10^{-6.}$
- Shelf-Life testing was completed *per*
  - *EN ISO 11607-1 EN 11607-1 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barriers and packaging systems* and
  - *EN ISO 11607-2 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.*
    - Demonstration of package integrity for materials, sterile barrier systems and packaging systems after gamma sterilization, distribution simulation and environmental conditioning.
- Endotoxin testing demonstrated that the iTrack™ Advance was able to meet FDA recommended endotoxin levels.
- Human Factors Engineering Evaluation was performed on the iTrack™ Advance per *IEC 62366-1 Part 1: Application of Usability*. The Validation Testing was completed successfully and there were no unacceptable use related risks remaining. The evaluation utilized trained surgeons in a simulated surgical environment, working through all stages of unpacking, presenting to sterile field, priming, and using the device as per instructions for use.
- An Endurance and Cycle Test was conducted to ensure that the device can withstand repeated advancement and withdrawal of the microcatheter from the handpiece. The

iTrack™ Advance was inserted into the anterior segment of the model eye ensuring catheter advancement of 360° around the canal and retracted. After completion of the cycle, the device was inspected for any compromised components. Results show that the device was able to meet acceptance criteria.

- Ex-Vivo and Simulated Use Testing - Simulated use testing in human cadaver eyes was performed using the iTrack™ Advance. The study was performed to demonstrate that the iTrack™ Advance is capable of 1) visualization of the illuminated microcatheter tip 2) ability to inject viscoelastic and 3) 360° cannulation. The study ensures that the device could be appropriately used by trained physicians as intended.
- Mechanical and Dimensional Testing -The microcatheter, cannula and handpiece were tested to verify several critical dimensions. Additionally, mechanical testing was performed including a drop test, verification of actuator retraction, pull force, tensile strength, burst test, fluid infusion, line leakage and aspiration testing verification. Results show that the device met all specifications and acceptance criteria.
- Actuator Force Testing – This testing was performed to evaluate the force required to advance and retract the microcatheter from the handpiece via the cannula and to establish limits for these forces.
- Light Hazard Assessment in accordance with *ANSI Z80.36 Light Protection for Ophthalmic Instruments* and *ISO 15752 Ophthalmic instruments – Endoilluminators Optical Radiation Safety Evaluation* was carried out.
    - The iTrack™ Advance is a Group 1 device for Light Hazard.

Conclusions

The iTrack™ Advance is substantially equivalent to the currently cleared predicate device iTrack 250A Ophthalmic Microcatheter. The changes to the subject device did not raise new questions of safety and efficacy of the device. The iTrack™ Advance maintains the same indications, intended use, target population, target anatomy, principle of operation and key technological characteristics as the predicate device. Based on the changes made as compared to the cleared predicate, it was appropriate to leverage the clinical data used in support of the cleared predicate device. The mechanism of action for both the predicate and subject device is the same. Both devices are manually operated and utilize a microcatheter with illuminated tip to access the Schlemm's canal and deliver viscoelastic fluid. Non-clinical human factors data demonstrate that the iTrack™ Advance performs as intended.