June 7, 2018

Carl Zeiss Meditec AG
% Becky Ditty
Consultant
Biologics Consulting
1555 King Street, Suite 300
Alexandria, Virginia 22314

Re: K180839
Trade/Device Name: AT 030
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: Class II
Product Code: HKY
Dated: March 30, 2018
Received: March 30, 2018

Dear Becky Ditty:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180839

Device Name
AT 030 Applanation Tonometer

Indications for Use *(Describe)*
The AT 030 is an appliance that serves to measure intraocular pressure, according to the Goldman method. Assessment of IOP may contribute to the diagnosis, and aid in the management of 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for AT 030 is provided below.

1. SUBMITTER

Applicant:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena Germany Tel: +49 3641 220
Contact:	Dr. Christian Münster Director Regulatory and Clinical Affairs +49 7364 20 6985 Christian.Muenster@zeiss.com
Submission Correspondent:	Becky Ditty Consultant Biologics Consulting 1555 King Street, Suite 300 Alexandria, VA 22314 bditty@biologicsconsulting.com Phone: (269) 888-2516
Date Prepared:	June 4, 2018

2. DEVICE

Device Trade Name:	AT 030
Device Common Name:	Applanation tonometer
Classification Name	21 CFR 886.1930 - Tonometer and Accessories
Regulatory Class:	II
Product Code:	HKY

3. PREDICATE DEVICES

Predicate Device:	Haag-Streit Goldmann manual tonometer (AT 900. Models R, t, BQ): K981432

4. DEVICE DESCRIPTION

The AT 030 applanation tonometer serves for measuring intraocular pressure, following the principle introduced by Professor Goldmann.

The AT 030 consists of the applanation tonometer with a measuring prism. The measuring prism, which includes a built-in optical doubling system, can be attached to the tonometer via the extensible measuring prism holder. The prism contacts the patient´s cornea and the applanation surface is observed through the stereomicroscope of the slit lamps. The rotary knob of the graduated drum allows the user to vary the applied force. A scale on the tonometer indicates a value that can be converted into the intraocular pressure by using the conversion table supplied in the Instruction for Use.

The AT 030 applanation tonometer is compatible with the following ZEISS slit lamps: SL 120 (K133476), SL 130 (K133476), SL 220 (K162684), LSL VISULAS 532s (K013402), and LSL VISULAS 532s vite (K100035). The AT 030 works solely mechanically.

5. RISK MANAGEMENT

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by design means, protection measures and user instructions. To confirm that the measures are effective and that the device meets its intended use, verification of requirements and standards was performed. Carl Zeiss Meditec adheres to recognized and established industry practice and relevant international standards where indicated.

6. INDICATIONS FOR USE

The AT 030 is an appliance that serves to measure intraocular pressure, according to the Goldman method. Assessment of IOP may contribute to the diagnosis, and aid in the management of glaucoma.

7. TECHNOLOGICAL COMPARISON

The essential characteristics are shown within the below table.

	SUBJECT DEVICE	PREDICATE DEVICE
FEATURE	AT 030	GOLDMANN MANUAL TONOMETER AT 900 / HAAG-STREIT AG (K981432)
Operation principle	Goldmann Tonometer	Goldmann Tonometer
Type	Manual contact tonometer	Manual contact tonometer
Indication	Intraocular Pressure (IOP) measurement	Intraocular Pressure (IOP) measurement
Type of Pressure Transducer	Measuring Prism	Measuring Prism
Measuring Prism	Article#: HSC 1000855 Identical / unmodified	Article#: HSC 1000855 Cleared in K981432
Prism Material	Acrylic (PMMA)	Acrylic (PMMA)
Measurement technique	The measuring of the pressure requires to maintain a uniform applanation of the surface of the cornea.	The measuring of the pressure requires to maintain a uniform applanation of the surface of the cornea.
Applanation surface diameter	3.06 mm	3.06 mm
Measurement Range	2 – 80 mm Hg	0 – 80 mm Hg
Measurement reading	reading the value multiplying x 10 yields the IOP in mm Hg	reading of the value, multiplying x 10 yields the IOP in mm Hg
Accuracy and repeatability	The measurement deviation in the measuring prism is in the measuring range from 0 – 58.84 mN and amounts to a maximum of ±1.5% and to a minimum of ±0.49 mN of the nominal value	The measurement deviation in the measuring prism is in the measuring range from 0 – 58.84 mN and amounts to a maximum of ±1.5% and to a minimum of ±0.49 mN of the nominal value

8. PERFORMANCE DATA

Biocompatibility Testing

The AT 030 is a surface contacting device intended for limited contact with intact corneas. The device is intended for limited contact duration. The AT 030 is identical in patient contacting materials as the predicate device, therefore no new biocompatibility testing is necessary.

Sterilization

The AT 030 is used non-sterile and sterilization is not applicable. Service life, cleaning and disinfection process is identical to the predicate device.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing is not applicable. AT 030 does not contain electrical components.

Software

Software verification and validation is not applicable. The AT 030 device does not include software.

Bench Testing

The AT 030 has been tested and shown to comply with the applicable requirements of ANSI Z 80.10-2014 Ophthalmic Instruments – Tonometers. The AT 030 meets the requirements of a reference tonometer as specified in Annex A of ANSI Z80.10.

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

9. CONCLUSION

AT 030 has the same intended use and technological characteristics as the predicate device AT 900 manufactured by Haag-Streit AG (K981432).

The differences in technological characteristics does not raise new questions of safety and effectiveness. ZEISS believes that the subject device AT 030 is substantially equivalent to the predicate device.