May 16, 2019

Santec Corporation
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, NJ 07059

Re: K191051
Trade/Device Name: Argos
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: MXK
Dated: April 17, 2019
Received: April 19, 2019

Dear Dave Yungvirt:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

for Malvina B. Eydelman, M.D.
Director
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K191051

Device Name
ARGOS (ARGOS ver1.5)

Indications for Use *(Describe)*

ARGOS is a non-invasive, non-contact biometer based on swept-source optical coherence tomography (SS-OCT). The device is intended to acquire ocular measurements as well as perform calculations to determine the appropriate intraocular lens (IOL) power and type for implantation during intraocular lens placement. ARGOS measures the following 9 parameters: Axial Length, Corneal Thickness, Anterior Chamber Depth, Lens Thickness, K-values (Radii of flattest and steepest meridians), Astigmatism, White-to-white (corneal diameter) and Pupil Size. The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool.
It is intended for use by ophthalmologists, physicians, and other eye-care professionals and may only be used under the supervision of a physician.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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510(k) SUMMARY

The information contained in this premarket notification 510(k) summary is submitted as required by 21 CFR 807.92:

1. Type of Submission

510k Traditional submission for New Devices

2. Applicant Company:

SANTEC CORPORATION
5823 Ohkusa-Nenjozaka,
Komaki, Aichi 485-0802, JAPAN
Phone: 81 (0568) 79 3535
www.santec.com

3. Applicant (Contact Person) Name:

Changho Chong

4. Date Summary Prepared:

May 15, 2019

5. Device Trade / Proprietary Name (Model name):

ARGOS (ARGOS ver1.5)

6. Common Name:

Optical Biometer

7. Regulation

Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Bio-Microscope
Regulatory Class: Class II
Product Code: MXK

8. Indications for Use:

ARGOS is a non-invasive, non-contact biometer based on swept-source optical coherence tomography (SS-OCT). The device is intended to acquire ocular measurements as well as perform calculations to determine the appropriate intraocular lens (IOL) power and type for implantation during intraocular lens placement. ARGOS measures the following 9 parameters: Axial Length, Corneal Thickness, Anterior Chamber Depth, Lens Thickness, K- values (Radii of flattest and steepest meridians), Astigmatism, White-to-white (corneal diameter) and Pupil Size. The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool.
It is intended for use by ophthalmologists, physicians, and other eye-care professionals and may only be used under the supervision of a physician.

The indications for use are similar between the proposed and predicate ARGOS devices. The proposed ARGOS device has additional reference image functionality as minor difference.

9. Device Descriptive

The ARGOS is substantially equivalent to the predicate device identified previously:

- the ARGOS (Santec Corporation) that was cleared by the FDA on October 2nd, 2015(K150754) as the primary predicate as it has the most similar intended use and characteristics
- the IOLMaster 700 (Carl Zeiss Meditec) that was cleared by the FDA on June 29, 2015 (K143275, K170171) as an additional (secondary) predicate to support a new feature of reference image capture on the version of ARGOS in this submission.

The predicate devices are Class 2 devices to premarket notification, as defined per regulation number 21 CFR 886.1850. In addition, the predicate devices have product codes of MXK(ARGOS), and HJO(IOLMaster700).
The version of ARGOS in this submission is a modified version of the Argos cleared under K150754 which is substantially equivalent with regard to intended use, operating principle, function, materials, and energy source. The differences from the predicate ARGOS (K150754) that are subject of this 510(k) submission are:

- An additional feature of reference image capture function
- Labeling change including change in the intended use adding the feature of reference image capture.
- This image can be transferred to image guided devices in order to support the execution of preoperative plan.

The changes described in this submission do not affect how the hardware is used to acquire measurements as a biometer, nor do these changes affect the principle of operation of the device.

10. Guidance on the Recognition and Use of Consensus Standards:

ARGOS complies with the requirements of listed FDA Recognized Consensus Standards.

Compliant standard	Description	Classification
ANSI/AAMI ES 60601-1	Electrical safety	Class 1 Type B
IEC 60601-1-2	Electrical safety	Refer to Appendix 4
IEC 60529	Housing protection	IP20
ANSI.Z80-36	Ophthalmics - Light Hazard Protection For Ophthalmic Instruments	Group 2
IEC 62471	LED light hazard	Exempt group
IEC 60825-1	Laser product safety	Laser Class 1
ISO 10343	Ophthalmometer	

11. Substantial equivalence to the predicate device

11.1 Comparisons of technological characteristics with Predicate ARGOS devices

Table of Comparison between the ARGOS and the Predicate Device

	New Device (Subjective device)	Primary Predicate Device	Secondary Predicate device	Comparison
Manufacturer	santec corporation	santec corporation	Zeiss Meditech	-
Model	ARGOS ver1.5	ARGOS	IOLMaster 700	-
510(k) number		K150754	K143275, K170171	-
Class	II	II	II	Same
Classification panel	Ophthalmic device panel	Ophthalmic device panel	Ophthalmic device panel	Same
Product code	MXK	MXK	HJO	Same
Classification number	AC-Powered Slitlamp Bio-Microscope	Device, Analysis, Anterior Segment	AC-Powered Slitlamp Bio-Microscope	Same
Type	Optical biometer	Optical biometer	Biometer	Same
Intended Use	ARGOS is a non-invasive, non-contact biometer based on swept-source optical coherence tomography (SS-OCT). The device is intended to acquire ocular measurements as well as perform calculations to determine the appropriate intraocular lens (IOL) power and type for implantation during intraocular lens placement. ARGOS measures the following 9 parameters: Axial Length, Corneal Thickness, Anterior Chamber Depth, Lens Thickness, K-values (Radii of flattest and steepest meridians), Astigmatism, White-to-white (corneal diameter) and Pupil Size. The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool. It is intended for use by ophthalmologists, physicians, and other eye-care professionals and may only be used under the supervision of a physician.	ARGOS is a non-invasive, non-contact biometer based on swept-source optical coherence tomography (SS-OCT). The device is intended to acquire ocular measurements as well as perform calculations to determine the appropriate intraocular lens (IOL) power and type for implantation during intraocular lens placement. ARGOS measures the following 9 parameters: Axial Length, Corneal Thickness, Anterior Chamber Depth, Lens Thickness, K-values (Radii of flattest and steepest meridians), Astigmatism, White-to-white (corneal diameter) and Pupil Size. It is intended for use by ophthalmologists, physicians, and other eye-care professionals and may only be used under the supervision of a physician.	The indications for use are identical between the subject and predicate IOLMaster 700 devices. The IOLMaster 700 is intended for biometric measurements and visualization of ocular structures. The measurements and visualization assist in the determination of the appropriate power and type of intraocular lens. The IOLMaster 700 measures: • Lens thickness • Corneal curvature and thickness • Axial length • Anterior chamber depth • Pupil diameter • White-to-white distance (WTW) For visualization, the IOLMaster 700 employs optical coherence tomography (OCT) to obtain two-dimensional images of ocular structures of the anterior and posterior segments of the eye. The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool.	Similar to Primary, additional feature identical to secondary predicate
Measured parameters	Axial Length, Corneal Thickness, Anterior Chamber Depth, Lens Thickness, K-values (Radii of flattest and steepest meridians), Astigmatism (Toric Angle), White-to-white (corneal diameter), and Pupil Size.	Axial Length, Corneal Thickness, Anterior Chamber Depth, Lens Thickness, K-values (Radii of flattest and steepest meridians), Astigmatism (Toric Angle), White-to-white (corneal diameter), and Pupil Size.	Lens thickness, Corneal curvature and thickness, Axial length, Anterior chamber depth,Pupil diameter, White-to-white distance (WTW)	Same parameters
In-vivo repeatability	Axial length: range 14-38mm, SD 0.01mm	Axial length: range 14-38mm, SD 0.01mm	Axial length: range 14-38mm, SD 0.005mm	Same between subjective and primary, Similar between subjective and secondary predicate
	Corneal thickness: range 200-120um, SD 10um	Corneal thickness: range 200-120um, SD 10um	Corneal thickness: range 200-120um, SD 2.5um	
	Anterior Chamber Depth: range 0.7-8.0mm SD 0.01mm	Anterior Chamber Depth: range 0.7-8.0mm SD 0.01mm	Anterior Chamber Depth: range 0.7-8mm SD 0.007mm	
	Lens Thickness: range 0.5-10.0mm SD 0.02mm	Lens Thickness: range 0.5-10.0mm SD 0.02mm	Lens Thickness: range 1-10.0mm SD 0.006mm	
	Keratometry: range 5.5-10.0mm SD 0.02mm	Keratometry: range 5.5-10.0mm SD 0.02mm	Keratometry: range 5-11.0mm SD 0.09D(~0.02mm)	
	Astigmatism: range 0-180deg, SD 5deg (Cylinder>1D)	Astigmatism: range 0-180deg, SD 5deg (Cylinder>1D)	Astigmatism: range 0-180deg, SD 3.8deg (Cylinder>0.75D)	
	Pupil size: range 2-13mm SD 0.09mm	Pupil size: range 2-13mm SD 0.09mm	Pupil size: (no specification available)	
	White-to-White: range 7-15mm SD 0.06mm	White-to-White: range 7-15mm SD 0.06mm	White-to-White: range 8-16mm SD 0.111mm	

Method for biometry	Interferometry (SS-OCT)	Interferometry (SS-OCT)	Interferometry (SS-OCT)	Same
Method for keratometry	Video keratometry (16 LED)	Video keratometry (16 LED)	Video keratometry (IR LED)	Same
Optical radiation				
Type of light source	Wavelength swept laser (3kHz swept rate)	Wavelength swept laser (3kHz swept rate)	Wavelength swept laser (2kHz swept rate)	Same
	Wavelength 1060nm	Wavelength 1060nm	Wavelength 1055nm	Same
	Power <0.72mW (<0.1mW average at 1mm aperture during B-scan)	Power <0.72mW (<0.1mW average at 1mm aperture during B-scan)	unavailable	Same
Laser class	Class 1 (IEC 60825) ANSI-Z80.36-2016 Group2	Class 1 (IEC 60825) ISO15004-2 Group2	Class 1 (IEC 60825) ISO15004-2 Group2	Same (ANSI.Z80-36 is equivalent to ISO15004-2)
Keratometry	Light source: IR-LED Wavelength: 850nm delivered power <0.02mW	Light source: IR-LED Wavelength: 850nm delivered power <0.02mW	Light source: IR-LED Wavelength: 950nm	Same between Primary and subjective
Illumination	The above (IR-LED) White LED for reference image	The above (IR-LED)	The above (IR-LED) Green LED(590nm) for reference image	Different
Fixation light	Red(630nm) delivered power <10nW	Green LED (530nm) delivered power <10nW	Red(660nm) delivered power	Different
Compliant standards	ANSI/AAMI ES 60601-1, ANSI.Z80-36, ISO62471, ISO60825, ISO 10343, IP20	ANSI/AAMI ES 60601-1, ISO15004-2, ISO62471, ISO60825, ISO 10343, IP20	ANSI/AAMI ES 60601-1, ISO15004-2, ISO60825	Same
Power supply	Input: 100-240V, 50/60Hz I ANSI/AAMI ES 60601 compliant Secondary side: 24V	Input: 100-240V, 50/60Hz ANSI/AAMI ES 60601 compliant Secondary side: 24V	Input: 100-240V, 50/60Hz ANSI/AAMI ES 60601 compliant Secondary side: 24V	Same
Accessories	Calibration tool/ Dust cover	Calibration tool/ Dust cover	----	Same

11.2 Summary of Differences

Model	Proposed ARGOS	Predicate ARGOS	Secondary(IOLMaster700)
Intended use	The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool.	Camera image was present for alignment purpose but not for capture.	The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool.
Light source for illumination	LED 16 @ 850nm LED 8 @ white light	LED 16 @ 850nm	IR LEDs@ 950nm Green LEDs @590nm
Fixation LED	LED @ 630nm	LED @ 530nm	LED @ 660nm

Software difference between Proposed Argos 1.5 and Predicate Argos

Model	Proposed ARGOS	Predicate ARGOS	Note
Software components	Vision Planner software package Argos UI software	Argos UI software	Different
Interface UI	Patient planning(patient information entry, summary, IOL power calculation/setting) Constant optimization Measurement with reference image capture Analysis	Patient information entry Summary IOL power calculation/setting Constant optimization Measurement Analysis	Similar Different Same
Connection to external device	Connectivity to Verion devices, ORA system	n.a.	Different

Analysis of Why These Differences Do Not Affect Safety or Effectiveness or Raise Different Questions of Safety or Effectiveness

Differences	Analysis
Intended use adding Reference image capture	The Reference Image functionality is intended for use as a preoperative and postoperative image capture tool. This image is used for optional guidance for planning subsequent surgical planning, but no association to biometer measurement itself. Subjective quality check is done by the user and the user can repeat the capture. Secondary predicate (IOLMaster700, K143275) has the same description of functionality in the intended use.
LED 8 @ white LED for the above reference image capture	For power level, duration of white flash illumination for the above mentioned reference image capture is very short (<0.25sec) and exposure is well below permissible exposure limits set by the standards and all compliant with IEC60825, ANSI.Z80.36. Testing based on ANSI Z80.36 demonstrated that the ARGOS near-infrared radiation from a swept source is below all of the applicable exposure limits-including the guidelines for the Group 1 ophthalmic instrument for normal use and Group 2 only for single fault case. This capture is done successively after biometry/keratometry measurement and has no effect on the measurement itself.
Fixation LED @630nm	Very low power, parts identified as exempt from ISO 62471. It is assured that the power level is within ANSI.Z80-36 criteria.
Software module	Vision Planner software package acts as interface for the proposed Argos ver1.5 but contains common functionalities (Patient information entry, IOL power calculation/setting, constant optimization) found in Predicated Argos. Software integration with Vision Planner software package and Argos software was validated and its usability including reference image capture was evaluated. It was found to achieve comparable usability to predicate Argos. (Section 22 Performance Testing-Bench, Appendix 13 Usability evaluation report), Additional connectivity to external device is validated in system level test. (Appendix 12. Software Documents for Vision Planner)

11.3 Substantial Equivalence Conclusion

Comparisons and analysis of technological characteristics of the proposed ARGOS with Predicate ARGOS devices were performed and found to be substantially equivalent.

12. Performance Testing

12.1 Bench Test
Performance of the ARGOS was evaluated by bench tests based on the relevant standards (ISO15004-1, ANSI.Z80-36, IEC 60825, ISO 10343).
Both ISO 15004-1 and ANSI.Z80-36, and IEC60825 tests prove the fundamental requirements for ophthalmic instruments and optical radiation safety of ARGOS are equivalent to predicate device. ISO 10343 tests results provided the required accuracy performance for ophthalmometer which measures corneal radii of curvature and angle of meridian with a certain cylinder (toroidal surface).
Hardware specifications were validated for axial/lateral distance measurement accuracy and range, signal-to-noise ratio, and depth attenuation, to prove that ARGOS meets the hardware performance requirements.

In addition, usability of the system including user interface software was evaluated and validated. Usability engineering conforms to IEC 62366, a collateral standard of ANSI/AAMI ES 60601-1.

12.2 Software Verification and Validation
Software verification and validation were performed according to ISO14971 and FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005). The verification and validation results confirm the fulfillment of software requirement specifications.

12.3 Cybersecurity review
Cybersecurity hazard analysis and risk management were conducted according to FDA guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" (Oct 2, 2014).

12.4 Conclusion drawn from Performance Testing and Software verification and validation
The summary of bench tests and software verification and validation showed that the ARGOS was substantially equivalent to the predicate ARGOS devices -Information was submitted to demonstrate that there are no significant differences in technological characteristics between the proposed ARGOS and the predicate ARGOS devices.

13. Conclusion:
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this Premarket Notification, Santec Corporation concludes that the ARGOS is safe and effective, and substantially equivalent to predicate devices as described herein.

END OF SUMMARY