July 17, 2026

Carl Zeiss Meditec, AG
% Marysa Lyew
Regulatory Affairs Manager
Carl Zeiss Meditec USA, Inc.
5300 Central Pkwy.
Dublin, California 94568

Re: K260694
Trade/Device Name: Zeiss Clinic 360
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: NFJ
Dated: March 3, 2026
Received: March 3, 2026

Dear Marysa Lyew:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

BRADLEY S. CUNNINGHAM -S

CAPT Brad Cunningham, MSE, RAC
Acting Assistant 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260694

Please provide the device trade name(s).

ZEISS CLINIC 360

Please provide your Indications for Use below.

ZEISS CLINIC 360 is comprehensive software intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management and display of patient data, diagnostic data, clinical information, and reports from ophthalmic diagnostic instruments through computerized networks.

The device aids in the detection, monitoring and management of various ocular diseases.

Please select the types of uses (select one or both, as applicable).

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

1.0 Contact Details

Applicant Name: Carl ZEISS Meditec AG

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Applicant Contact Telephone: +1 925-236-1195

Applicant Contact: Mr. Todd Milholland

Applicant Contact Email: todd.milholland@zeiss.com

Correspondent Name: Carl ZEISS Meditec USA Inc.

Correspondent Address: 5300 Central Parkway Dublin, CA. 94568, United States

Correspondent Contact Telephone: +1 925-413-8108

Correspondent Contact: Ms. Marysa Lyew

Correspondent Contact Email: marysa.lyew@zeiss.com

2.0 Device Name

Device Trade Name: ZEISS Clinic 360

Common Name: ZEISS Clinic 360

Classification Name: Ophthalmic

Regulation Number: 892.2050

Product Code(s): NFJ

3.0 Legally Marketed Predicate Devices

Predicate # - Predicate Tade Name (Primary Predicate is listed first) – Product Code

K232555 – Harmony – NFJ

K233933 – CIRRUS™ HD-OCT Model 6000 – OBO

K093213 – GPA on the HUMPHREY FIELD ANALYZER II & II-I Series – HPT

4.0 Device Description Summary

ZEISS CLINIC 360 is a browser-based software designed to consolidate, process, analyze and display patient medical and diagnostic data. It integrates data stored in the Health Data Platform

(HDP) allowing users to access and review comprehensive diagnostic information. HDP is a separate non-medical device platform that will support CLINIC 360. The Health Data Platform (HDP) provides a workflow enabling bi-directional data flow between medical devices or health record systems with cloud-based clinical and administrative applications.

ZEISS CLINIC 360 builds upon feature sets available in CIRRUS (K233933) and HFA (K093213) by leveraging raw data analyses and integrating the data into one integrated multimodal view. ZEISS CLINIC 360 implements CIRRUS algorithms (OCT Analyzer) and reference databases for macular thickness, retinal nerve fiber layer thickness, ganglion cell plus inner plexiform thickness, optic nerve head measurement. CLINIC 360 also implements Humphrey Field Analyzer (HFA) algorithms and databases for visual field measurements and Visual Field Guided Progression Analysis. Visual Field Guided Progression Analysis (GPA) for HFA is a functionality designed to help clinicians identify and quantify statistically significant progressive visual field loss in glaucoma patients.

ZEISS CLINIC 360 is designed to support the clinician in the detection, monitoring, and management of various ocular diseases. It provides annotation tools and enables the health care provider to adjust parameters such as brightness and contrast, as well as utilize zoom and planning. Furthermore, through the use of tags, clinicians can document key decisions and annotate changes, which can then be transmitted back to the Electronic Medical Records (EMR), streamlining the documentation process.

ZEISS CLINIC 360 integrates with ZEISS Collaborative Care, a separate application, enabling users to share selected images with other health care providers by clicking the sharing button. This inter-application integration is achieved through the use of an application programing interface (API).

ZEISS CLINIC 360 does not acquire any diagnostic data by itself and is not connected directly to any computerized diagnostic instruments (e.g. a CIRRUS HD-OCT).

ZEISS CLINIC 360 will be delivered in the following subscription offerings, targeting specific customer groups:

1. Primary Care Workflow – focused on Basic Care markets providing multi-modality connectivity and visualization, standard OCT, and Fundus imaging visualization.
2. Comprehensive Care Workflow – focused on Intermediate Care markets providing multi-modality connectivity and visualization, advanced OCT and Fundus imaging visualization, and support for management of mild and moderate glaucoma.

Key functional elements of ZEISS Clinic 360 include the following.

Patient Overview: Patient Overview Screen gives the user contextual information about the patient. It consolidates the medical and diagnostic data into a single screen, giving an overview of the patient's data to be used for the assessment process.

Disease Summary: The Disease Summary is only provided for glaucoma in the Comprehensive Care subscription, as glaucoma involves complex statistical analysis. ZEISS CLINIC 360 will make a disease summary available by either using the diagnosis from EMR or tags, or by checking if the data is required for the disease summary is present.

The Glaucoma Summary offers the functionality of processing and displaying HFA visual field data, including the Guided Progression Analysis (GPA). The Glaucoma Summary aids the clinician in the detection, monitoring, and management of glaucoma and its progression as well as providing means to annotate and flag data according to the clinicians' needs. Visual Field Guided Progression Analysis (GPA) for HFA is a functionality designed to help clinicians identify and quantify statistically significant progressive visual field loss in glaucoma patients. CLINIC 360 provides GPA trend analyses through HFA Analyzer Software component with the goal of quantifying how quickly each patient's visual fields are changing (the rate of visual field loss) and to help the practitioner assess the risk of future visual impairment associated with that rate of change.

Diagnostic Visualization – Multi-Modality Diagnostic Image Viewing: ZEISS CLINIC 360 will provide a comprehensive set of image viewing capabilities. It will take advantage of the algorithms and reference databases of well-established Carl Zeiss Meditec products - CIRRUS OCTs and HFA – and display the corresponding data points.

Reference Database (RDB) Analytics: The reference databases provide quantitative metrics to aid clinicians in differentiating between healthy and pathological conditions, and it also assists clinicians in the diagnosis and management of ocular conditions. The reference database used in CLINIC 360 can be turned on or off based on preference. RDB1 is the existing legacy diversified database that associates CIRRUS 400/4000/500/5000 study data to compare macular thickness, ganglion cell thickness, optic disc, and RNFL measurements to a reference range for healthy eyes for a patient's age. RDB2 is a diversified reference database created for CIRRUS 6000 to help clinicians assess and compare a patient's measurements to a database of healthy subjects.

Macular Single Eye Analysis: Macular Single Eye Analysis or Macular Thickness Analysis (MTA) analyzes data for a single eye's macular exam by using CIRRUS OCT algorithms implemented by OCT Analyzer.

Optic Disc Analysis: The ONH OCT Viewer allows a clinician to view structural scans of the Optic Nerve Head (or Optic Disc). It leverages the CIRRUS Optic Disc 200 x 200 scan to measure the structure of the Optic Nerve. This scan is used to assess optic nerve health and look for signs of glaucoma.

Wellness Analysis: Wellness analysis is a single page display that provides an integrated OU assessment of macular thickness, RNFL thickness, GCL/IPL thickness, and optic nerve head parameters compared to a reference database of healthy subjects from CIRRUS. Wellness Analysis displays a combined or stitched view called the PanoMap analysis which combines information from the Macular Thickness analysis, RNFL and ONH analysis, and GCL/IPL

analysis to provide an integrated, wide-field perspective for comprehensive analysis for both eyes.

MOR Report(s): The MOR report feature, from CIRRUS data, provides an integrated display of RNFL thickness, GCL/IPL thickness, RNFL deviation map, and GCL/IPL deviation map compared to a reference database of healthy subjects for the evaluation of glaucoma. The MOR Report is available for a single eye or both eyes. It provides a quantification/analysis tools for each of the supported scan types to help support glaucoma detection and progression.

Raster Scans: OCT Analyzer also provides a function to display raster scans. Raster Scans provide higher averaging and better resolution than an OCT cube scan. This is not an analysis feature but only a display of the B-Scans. With this feature, the user can review different raster scan patterns acquired on CIRRUS devices.

Image Review and Comparison Tools: ZEISS CLINIC 360 provides review tools that allow users to enhance specific structural details of images by improving contrast between different structures to focus on areas of interest. ZEISS CLINIC 360 offers a comprehensive set of tools designed to enhance image viewing and manipulation experience.

Clinical Documentation through Tagging: ZEISS CLINIC 360 offers the functionality of tagging to document clinical assessment and treatment decisions. Tagging refers to the functionality that allows users to assign specific labels or tags to diagnosis, findings, and medication.

A comparison of the software capabilities available for ZEISS vs. Non-ZEISS images are provided in the table below:

Feature Availability by Image Source

Feature Category	Feature	ZEISS Images	Non-ZEISS Images	Acceptance Criteria
Visualization	Zoom / Pan	Yes	Yes	DICOM compliant image
Visualization	Print	Yes	Yes	DICOM compliant image
Visualization	Download	Yes	Yes	DICOM compliant image
Visualization	B-scan navigation	Yes	Yes	DICOM OPT image
Analysis	OCT Quantitative Analysis (Deviation Map, RNFL Thickness Map, GCL+IPL Thickness Map, ETDRS Grid, Quadrant Average, Clock Hour Average, RNFL Thickness Chart, Layer (Segmentation), Comparison with Normative Reference Data,)	Yes from ZEISS CIRRUS only	No	ZEISS CIRRUS OCT raw DICOM data
Analysis	Visual Field Analysis (VFI value and Regression and Progression for VFI, Mean Deviation Value and Slope, PSD value, Event Analysis)	Yes from ZEISS HFA only	No	ZEISS HFA raw DICOM data from supported models (HFA II, HFA II-i, HFA 3)

5.0 Indications for Use

ZEISS CLINIC 360 is comprehensive software intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management and display of patient data, diagnostic data, clinical information, and reports from ophthalmic diagnostic instruments through computerized networks. The device aids in the detection, monitoring and management of various ocular diseases.

6.0 Indications for Use Comparison

The subject device (ZEISS CLINIC 360) and the predicate device (Harmony;K232555) are both comprehensive software intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management and display of patient data, diagnostic data, clinical information, and reports from ophthalmic diagnostic instruments through computerized networks. They are both Cloud (browser based) DICOM-enabled devices that are IEC 62304 Compliant.

7.0 Technological Comparison

ZEISS CLINIC 360 builds upon feature sets available in CIRRUS (K233933) and Humphrey Field Analyzer (K093213) by leveraging raw data analyses and integrating the data into one integrated multimodal view. ZEISS CLINIC 360 implements CIRRUS algorithms (OCT

Analyzer) and reference databases, as well as algorithms and databases from HFA for visual field measurements and Visual Field Guided Progression Analysis.

The technological characteristics and risk profile of the subject device (ZEISS CLINIC 360) are equivalent in their relationship to safety and effectiveness to the predicate device (Harmony; K232555) and the listed reference devices (CIRRUS; K233933) and (HFA; K093213).

Therefore, the subject device can be determined to be substantially equivalent to the predicate.

The Substantial Equivalence Table for the Subject Device and its Primary Predicates and Reference Devices is provided below:

Substantial Equivalence of ZEISS Clinic 360 to Predicate(s)

Attributes / Specifications	Subject Device: Clinic 360 v. 1.0 (KTBD)	Predicate Device: Harmony (K232555)	Reference Device 1: Cirrus HD-OCT 6000 v.11.7 (K233933)	Reference Device 2: HFA II, HFA II-i (K093213)	SE Analysis
Device Classification	System, image management, ophthalmic	System, image management, ophthalmic	N/A	N/A	Same
Product Code	NFJ	Same	N/A	N/A	Same
CFR Regulation	21 CFR 892.2050	Same	N/A	N/A	Same
Classification	II	Same	N/A	N/A	Same
Indications for Use	Clinic 360 is a comprehensive software intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management and display of patient data, diagnostic data, clinical information, and reports from ophthalmic diagnostic instruments through computerized networks. The device aids in the detection, monitoring and management of various ocular diseases.	Harmony is a comprehensive software platform intended for use in importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments or through computerized networks.	The CIRRUS™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures, including cornea, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, and optic nerve head. The CIRRUS™ HD-OCT Reference Database is a quantitative tool used for the comparison of retinal nerve fiber layer thickness, macular thickness, ganglion cell	The Carl Zeiss Meditec, Inc. Guided Progression Analysis is a software analysis module for the Humphrey® Field Analyzer 1I (HFA H1) and Humphrey® Field Analyzer II - i series (HFA II - i) that assists practitioners with the detection, measurement, and management of progression of visual field loss. It aids in assessing change over time, including change from baseline and rate of change. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, glaucoma.	Same as Primary Predicate Minor differences in wording are clarifying in nature and do not alter the intended use or impact the S&E of the Subject Device.

Attributes / Specifications	Subject Device: Clinic 360 v. 1.0 (KTBD)	Predicate Device: Harmony (K232555)	Reference Device 1: Cirrus HD-OCT 6000 v.11.7 (K233933)	Reference Device 2: HFA II, HFA II-i (K093213)	SE Analysis
			plus inner plexiform layer thickness, and optic nerve head measurements to a database of healthy subjects. CIRRUS™ HD-OCT AngioPlex angiography is indicated as an aid in the visualization of vascular structures of the retina and choroid. The CIRRUS™ HD-OCT is indicated for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.		
Device Compatibility	• Optical Coherence Tomography devices • Mydriatic retinal cameras • Non-mydriatic retinal cameras • Biomicroscopes (slit lamps)	Same	N/A	N/A	Same
Testing	SW V&V, Usability, IEC 62304	V&V, IEC 62304	N/A	N/A	Different, no impact on S&E

Attributes / Specifications	Subject Device: Clinic 360 v. 1.0 (KTBD)	Predicate Device: Harmony (K232555)	Reference Device 1: Cirrus HD-OCT 6000 v.11.7 (K233933)	Reference Device 2: HFA II, HFA II-i (K093213)	SE Analysis
					Clinic 360 conducted a Usability Study
Platform/OS	Cloud (Browser Based)	Same	N/A	N/A	Same
Image/Data Transfer	DICOM enabled device	Same	N/A	N/A	Same
Image Modalities	OCT, Fundus, Perimetry, Biometry	Same	N/A	N/A	Same
Cybersecurity	User-level Permissions, encrypted data transfer	Same	N/A	N/A	Same
Interoperability	DICOM Network Integration	Same	N/A	N/A	Same
Modality Worklist	Collects, aggregates, and imports patient medical and demographic data from a connected EMR Collects scheduling data and send patient demographics to a device Imports of diagnostic data from various upstream devices (e.g., CIRRUS OCT) by Carl Zeiss Meditec	Same	N/A	N/A	Same
Image Review / Comparison Tools	<u>Primary Care:</u> - Brightness/contrast - Download image - Print images/reports - Synchronized zoom & pan <u>Comprehensive Care:</u> - Brightness/contrast - Download image - Print images/reports - Synchronized zoom & pan	- Brightness/contrast - Download image - Print images/reports - Synchronized zoom & pan - RGB split - Textual and graphical annotations - Image rotation	N/A	N/A	Same

Attributes / Specifications	Subject Device: Clinic 360 v. 1.0 (KTBD)	Predicate Device: Harmony (K232555)	Reference Device 1: Cirrus HD-OCT 6000 v.11.7 (K233933)	Reference Device 2: HFA II, HFA II-i (K093213)	SE Analysis
	- RGB split - Textual and graphical annotations - Image rotation				
Tagging	Tagging refers to the functionality that allows users to assign specific labels or tags	Same	N/A	N/A	Same
Diagnostic Visualization	Primary Care: - Ability to review up to 2 images side-by-side Comprehensive Care: - Multi-modal view: up to 6 images side-by-side - FA/ICGA series in a proof sheet	Same, can provide multiple images side by side, exact number is unknown	N/A	N/A	Same
Glaucoma Summary	<u>Offered only with Comprehensive Care</u> The Glaucoma Summary in Clinic 360 displays analyzed data from HFA Analyzer and OCT Analyser the following: <u>HFA Data</u> Glaucome Hemifield Test (GHT) Guided Progression Analysis (GPA) Mean Deviation (MD) and Visual Field Index (VFI) trend plots <u>OCT Data</u> Average Cup/Disc Ratio	N/A	<u>OCT Data</u> o Average Cup/Disc Ratio o Average RNFL Thickness (overall average thickness trend that shows the overall average thickness from the CIRRUS RNFL Calculation Circle for each exam) o Average Thickness of GCL-IPL (overall average thickness of the GCL + IPL is calculated by dividing the selected GCA annulus into 6 sectors and taking the average for each exam)	<u>Visual Field Data:</u> o Graytone plot, Pattern deviation, Baseline o Deviation from Baseline and Guided Progression Analysis (GPA) o Display of the MD and VFI trend plots	Different, no impact on S&E IOP trending is specific to Clinic 360 GHT is specific to Clinic 360

Attributes / Specifications	Subject Device: Clinic 360 v. 1.0 (KTBD)	Predicate Device: Harmony (K232555)	Reference Device 1: Cirrus HD-OCT 6000 v.11.7 (K233933)	Reference Device 2: HFA II, HFA II-i (K093213)	SE Analysis
	Average RNFL Thickness Average Thickness of GCL-IPL Includes the presentation of intraocular pressure and historical treatment interventions from Electronic Medical Records (EMR)				
Reference Database Analytics	CIRRUS OCT measurements can be compared against the following reference data: o Reference database 1 (RDB1) o Reference database 2 (RDB2)	N/A	Same	N/A	Same
Macular Scan Analysis	Macular Single Eye Analysis or Macular Thickness Analysis (MTA) analyzes data from CIRRUS OCT Macular Cube 512x128 and 200x200 scans by using algorithms implemented by Clinic 360's OCT Analyzer.	N/A	Same	N/A	Same
Optic Disk Analysis	Optic Disc Analysis allows for the clinician to assess optic nerve health and look for signs of glaucoma by viewing structural scans of the Optic Nerve Head (or Optic Disc). It leverages the CIRRUS Optic Disc 200 x 200 scan to	N/A	Same	N/A	Same

Attributes / Specifications	Subject Device: Clinic 360 v. 1.0 (KTBD)	Predicate Device: Harmony (K232555)	Reference Device 1: Cirrus HD-OCT 6000 v.11.7 (K233933)	Reference Device 2: HFA II, HFA II-i (K093213)	SE Analysis
	measure the structure of the Optic Nerve				
Wellness Analysis	Wellness Analysis displays a combined or stitched view of data from the Macular Thickness analysis and Optic Disc Analysis, of both eyes, acquired on the same day	N/A	Same	N/A	Same

8.0 Conclusion

Software validation and verification testing demonstrate that ZEISS CLINIC 360 performs as intended and meets its specifications. Use Scenarios involving CLINIC 360 features were validated in a moderated usability study with actual clinicians (optometrists, and ophthalmologists). Participants were directly observed performing tasks and actions necessary to use features in use scenarios. Observational use data was collected for each action performed. Ease-of-use ratings were collected upon the completion of each task. Any observed usability issues or negative observational ratings were subjected to a root cause analysis.

The CLINIC 360 usability validation study provided sufficient evidence that CLINIC 360 v1.0 features are safe and effective in use. All use scenarios met acceptance criteria and passed summative usability criteria. Observations of user interactions during representative use scenarios demonstrated that all tasks were performed without introducing new or previously unidentified hazards or risks.