June 15, 2021

Konan Medical, Inc.
℅ Alan Donald
President
Matrix Medical Consulting, INC.
8880 Rio San Diego Drive Suite 800
San Diego, California 92108

Re: K203244
Trade/Device Name: CellChek 20 rc
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: NFJ, NQE
Dated: April 20, 2021
Received: April 21, 2021

Dear Alan Donald:

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,

for Elvin Ng
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

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)*
K203244

Device Name
CellChek 20 rc Software

Indications for Use *(Describe)*
The CellChek 20 rc is a software program intended to analyze ophthalmic images captured by the Konan Specular Microscope XVII for examination of corneal endothelium.

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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The following 510(k) Summary is being submitted in accordance with the Requirements of MDA 1990 and CFR 807.92.

510(k) Summary

Submitter Information

A. Company Name:	Konan Medical, Inc.
B. Company Address:	10-29, Miyanishicho, Nishinomiya Hyogo 662-0976, Japan
C. Company Phone:	+81-798-36-3456
D. Company Facsimile:	+81-798-26-1028
E. Contact Person:	Runa Emura
F. Date Summary Prepared:	June 10, 2021

Device Identification

A. Device Trade Name:	CellChek 20 rc
B. 510(k) number:	K203244
C. Common Name:	Computer system for analysis of specular microscope images
D. Classification Name(s):	System, Image Management, Ophthalmic
E. Classification Regulation(s):	892.2050
F. Device Class:	Class 2
G. Product Codes:	NFJ
H. Prescription (Rx) or OTC?	Rx
I. Advisory Panel:	Ophthalmic

Identification of Predicate Device

The predicate device is the Image Storage System, Model KSS-400, which was cleared by FDA under 510(k) number K081797 on Jan 22, 2009.

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Identification for Reference Device

The reference device is the Konan Specular Microscopy XVII, CellChek 20, which was cleared by FDA under 510(k) number K191558 on March 26, 2020.

A. Common Name:	Specular Microscope
B. Classification Name(s):	AC-powered slitlamp biomicroscope.
C. Classification Regulation(s):	886.1850
D. Device Class:	Class 2
E. Product Codes:	NQE
F. Prescription (Rx) or OTC?	Rx
G. Advisory Panel:	Ophthalmic

Device Description

Konan Medical has developed the CellChek 20 rc to provide photographic data taken exclusively by the Konan Specular Microscope XVII, CellChek 20, which was cleared by FDA under 510(k) number K191558 on Mar 26, 2020, to research and learning centers for the advancement of ophthalmic sciences and practice. The CellChek 20 rc was developed based on the software program of CellChek 20.

CellChek 20 rc is a software program to analyze ophthalmic images for examination of corneal endothelium. This has the cell counting analysis program, and allows for analysis of the images of the cell distribution of the eye.
The software program is installed on a general-use computer to analyze corneal endothelial images photographed exclusively by the Konan Specular Microscope XVII, CellChek 20. The analysis function is to calculate mainly the cell density, the coefficient of variation of cell area, and the percent hexagonality. In the manual methods, cornea endothelial cells and cell boundaries are actually identified by users. In the automatic methods, this software detects cells and cell boundaries, however, users can modify the detection results. During operating, the users interact with the software by visually placing dots in the center of each of cells and/or by tracing cell boundaries displayed on a computer screen, or use the automatic algorithm.

A. Common Name:	Computer system for analysis of specular microscope images
B. Classification Name(s):	System, Image Management, Ophthalmic

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C. Classification Regulation(s):	892.2050
D. Device Class:	Class 2
E. Product Codes:	NFJ
F. Prescription (Rx) or OTC?	Rx
G. Advisory Panel:	Ophthalmic

CellChek 20 rc was developed according to the harmonized standard for software, IEC 62304, and FDA requirements for software and cybersecurity for the 510(k) clearance. Additionally, risk analysis studies revealed no new risks for the CellChek 20 rc when compared to the predicate device.

As shown in the above, it is concluded that the safety and the performance of CellChek 20 rc is substantially assured.

Indication for Use

The CellChek 20 rc is a software program intended to analyze ophthalmic images captured by the Konan Specular Microscope XVII for examination of corneal endothelium.

Technological Characteristics

The CellChek 20 rc is substantially equivalent to the predicate device, the Image Storage System, Model KSS-400 as shown the below comparison table. Since the analytical functions of the CellChek 20 rc are the same as in the CellChek 20 (K191558), it is shown below as a reference device.

Comparative Table of Predicate and Reference Devices for the CellChek 20 rc			
Name	**Model KSS-400**	**CellChek 20**	**CellChek 20 rc**
510(k) No. (ID No.)	K081797	K191558	K203244
Device name registered	Image Storage System, Model KSS-400	Konan Specular Microscope XVII	CellChek 20 rc
Indications for Use	The KSS-400 Image Storage System is intended to be used for automated image analysis and data	The Konan Specular Microscope XVII, CellChek 20, is a non-contact ophthalmic microscope, optical	The CellChek 20 rc is a software program intended to analyze ophthalmic images captured by the Konan

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Comparative Table of Predicate and Reference Devices for the CellChek 20 rc			
Name	**Model KSS-400**	**CellChek 20**	**CellChek 20 rc**
	storage for corneal images taken with Konan specular microscopes.	pachymeter, and camera intended for examination of the corneal endothelium and for measurement of the thickness of the cornea.	Specular Microscope XVII for examination of corneal endothelium.
Computer used	General-use computer by User.	This device has a built-in computer.	General-use computer by User.
Analysis	· Auto trace method · Manual trace method · ---------- · Center method · ---------- · Flex Center method	· Auto trace method · Trace method · Auto center method · Center method · Auto F Center method · F Center method	· Auto trace method · Trace method · Auto center method · Center method · Auto F Center method · F Center method
Display and Storage of Analysis results and Images	Yes	Yes	Yes
Print of Analysis results and Images	Yes	Yes	Yes
Load (Import) of Images	Yes (Load)	Yes (Import)	Yes (Import)
Outboard (Export) of Analysis results and Images	Yes (Outboard)	Yes (Export)	Yes (Export)
Note			
CellChek 20 rc was developed based on the software program of CellChek 20 (K191558).			

Summary of Testing

Non-Clinical Performance Testing

The following testing was performed on the CellChek 20 rc which was the same software function standard as those for CellChek 20.

- CellChek 20 rc device was subjected to software testing in accordance with IEC62304.

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Conclusion

From the above, it is concluded that the CellChek 20 rc software is substantially equivalent in the intended use, Indications for Use, technology, and functionality of the predicate device, the Image Storage System, Model KSS-400.