% Marc Leppla
Director
Quantum Spectra LLC
501, Silverside Road St 105
Wilmington, Delaware 19809

June 2, 2020

Re: K200889
Trade/Device Name: Apple iMac 27" 5K Retina with PL4.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: PGY
Dated: January 21, 2020
Received: April 3, 2020

Dear Marc Leppla:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200889

Device Name
Apple iMac 27" 5K Retina with PL4.0

Indications for Use *(Describe)*
The Apple iMac 27" 5K Retina with PL4.0 is intended to be used for displaying and viewing medical images, for review and analysis by trained medical practitioners.
The device can NOT be used in mammography.
The device can NOT be used for a life-support system.
The device is intended for prescription use.

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 as required by 807.92

K200889

1. Company Identification

QUANTUM SPECTRA LLC
501 SILVERSIDE RD STE 105
WILMINGTON
DE 19809

2. Official Correspondent

Mr. Marc Leppla
President and CTO (Chief Technical Officer) marc@qs-group.net

3. Date of Submission
01/21/2020

4. Device Trade name
Apple iMac 27” 5k Retina with PL 4.0

5. Common/Usual Name
Image display system, Color LCD Monitor, image monitor/display

6. Classification Number
Medical displays classified in Class II per 21 CFR 892.2050
Classification Name: Picture Archiving and Communications System

7.Predicate device
Name: DELL UP3017 With QUBYX PerfectLum Bundle
Manufacturer: DELL and QUBYX
510(k) number: K171229
Classification Number: Medical displays classified in Class II per 21 CFR 892.2050
Classification Name: Picture Archiving and Communications System

8. Device description

The Apple iMac 27” 5k Retina with PerfectLum 4.0 (PL 4.0) is a computer with color display for medical viewing.

It is combined with QUBYX PerfectLum 4.0 and PerfectLum remote management, a user- friendly DICOM calibration and AAPM TG18 verification software suite. The software allows setting the display function to DICOM, displaying test pattern and performing acceptance and constancy tests.

9. Indications for use

The Apple iMac 27” 5k Retina with PerfectLum 4.0 (PL 4.0) is intended to be used for displaying and viewing medical images, for review and analysis by trained medical practitioners.
The device can NOT be used in mammography.
The device can NOT be used for a life-support system.
The device is intended for prescription use.

10. Comparison of technological characteristics

Specification	**Apple iMac 27” 5k Retina with PL 4.0**	**DELL UP3017 with PerfectLum**
Screen technology	Color IPS Retina	Color TFT LCD Panel (IPS)
Active screen size (diagonal)	68 cm / 27"	30"
Resolution	5120 x 2880	2560 x 1600
Pixel pitch	0.1167 mm	0.25 mm
Color imaging	Yes	Yes
Gray imaging	Yes	Yes
Maximum luminance	500 cd/m2	350 cd/m2
DICOM calibrated luminance	350 cd/m2	300 cd/m2
Contrast ratio (typical)	1000:1	1000:1
Intended use	The Apple iMac 27” 5k Retina with PL 4.0 is intended to be used for displaying and viewing medical images, for review and analysis by trained medical practitioners. The device can NOT be used in mammography. The device can NOT be used for a life-support system. The device does not contact with the patient	The DELL U3017 with QUBYX PerfectLum is intended to be used for displaying and viewing medical images, for review and analysis by trained medical practitioners. The DELL U3017 can be used only in conjunction with QUBYX PerfectLum. The device can not be used in primary image diagnosis in mammography. The device can not be used for a life-support system. The device does not contact with the patient

Details of testing:

To verify DICOM conformance, a DICOM conformance test was performed, using QUBYX PL 4.0 software and an X-Rite i1 Display Pro measurement device.
The test procedure was generated by the software in accordance with the requirements of the DICOM standard. It consisted of measurement steps, where the meter measured display's characteristics and the software recorded them. Then the software analyzed the results in comparison with target values, defined by DICOM standard, and generated the report, stating that the display is DICOM-conformant.

The display device has successfully passed DICOM conformance test, so it is compliant with DICOM Part 14 GSDF standard. So is the predicate device, so the two devices are substantially equivalent in this regard.

To verify AAPM TG18 conformance, an acceptance test was performed, using QUBYX PerfectLum software and an X-Rite i1 Display Pro measurement device.
The test procedure was generated by the software in accordance with the requirements of the AAPM TG18 standard and consisted of measurement and visual parts.

During the measurement steps, the meter measured display's characteristics and the software recorded them. During the visual steps, the user analyzed test patterns, generated by the software in accordance with AAPM standard. The software recorded the user's answers. Then the software analyzed the results in comparison with target values, defined by AAPM standard, and generated the report, stating that the display passes AAPM TG18 acceptance test.

The display device has successfully passed AAPM TG18 acceptance test, so it is compliant with AAPM TG18 standard and can be used as a primary category display for interpretation of medical images. The same is true for the predicate device, so the two devices are substantially equivalent in this regard.

Both devices have the same indications for use, except for predicate device it is not specified that it will not contact with the patient.
We can conclude that the new and predicate devices are substantially equivalent in terms of performance, indications for use, and principles of operation.

International standards: Directives: 2014/53/EU 2009/125/EC 2011/65/EU
Safety and Health: EN 60950-1:2006+A1:2010+A11:2009+A12:2011+A2:2013 EN 50665:2017
EMC: EN 301 489-1 V2.2.0 EN 301 489-17 V3.2.0
RF Spectrum Efficiency: EN 300 328 V2.1.1 , EN 301 893 V2.1.1 , EN 300 440 V2.1.1
Additional Compliance: RoHS: EN50581:2012 , Energy: Regulation 617/2013

Conclusion:

The comparison table shows that the subject device (Apple iMac 27” 5k Retina with PerfectLum 4.0) has the same intended use as the predicate. Although the devices have some different technological characteristics, as a higher resolution and higher maximum luminance, these differences do not make the subject device less safe and reliable, so the subject device fits for diagnostic use as the predicate device does.

Both devices are compliant with DICOM Part 14 GSDF and AAPM TG18 standards. To verify DICOM and AAPM compliance for the subject device, AAPM acceptance test and DICOM conformance test were also performed.