510(k) Summary

Altaravision, Inc. K190420

This 510(k) Summary is in conformance with 21CFR 807.92

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Device Name and Classification

Trade Name: NDŌHD High Definition Imaging System (NDŌHD)
Common Name: Picture Archiving Communications System (PACS)
Classification: Class II
Regulation Number: 892.2050- Picture Archiving and Communications System (PACS)
Classification Panel: Radiology
Product Code: LLZ

Predicate Device:

	Primary Predicate
Trade Name	NDŌHD High Definition Imaging System (NDŌHD)
Common Name	Picture Archiving Communications System (PACS)
510(k) Submitter / Holder	Altaravision, Inc.
510(k) Number	K131873
Regulation Number	892.2050- Picture Archiving and Communications System (PACS)
Classification Panel	Radiology
Product Code	LLZ

Device Description and Intended Use
The NDŌHD High Definition Imaging System (NDŌHD) previously acquired FDA clearance in 2013 as a Class II picture archiving and communication system that provides capabilities related to the acquisition, transfer, display, storage, and digital processing of images and videos (K131873). The NDŌHD High Definition Imaging System (NDŌHD) previously acquired FDA clearance in 2013 as a Class II picture archiving and communication system (K131873). Altaravision replaced off the shelf hardware components due to the hardware becoming obsolete. Altaravision also updated the NDŌHD software to enable use of the new hardware, improve the software user interface and conform to Apple's latest coding best practices.

The NDŌHD system is intended for viewing, acquiring, recording, archiving and retrieving video and still images of endoscopic and fluoroscopic procedures.

Indications for Use
The NDŌHD system is intended for viewing, acquiring, recording, archiving and retrieving video and still images of endoscopic and fluoroscopic procedures. The professionals or practitioners using this system would be medical doctors or clinicians such as speech pathologists. The device is a prescription device. The NDŌHD system is not intended to be used in an environment that requires sterilization.

Risk Analysis Method

Risk Management activities were completed following ISO 14971:2007 and ISO 14971:2012 and Altaravision's current Risk Management Procedure, SOP 1070, in order to assess the impact of the modification on the device and its components. A Risk Management Plan was created to identify the risk management team, the risk acceptability criteria, and the plan for completion of a risk assessment and risk management report. Hazards for the new system were identified systematically using the device safety characteristics, and reviewing known hazards and hazard categories. Hazards related to the use of off the shelf software were also incorporated in the Risk Assessment. Risk was then evaluated using the established risk acceptability criteria and taking into account current controls of the system. Risks were then further evaluated after additional controls were taken into account. From here, residual risk was evaluated, and it was determined if a risk benefit analysis was necessary. All risks were found to be acceptable, and no risk benefit analysis was necessary. After the completion of the Risk Assessment, the overall risk and residual risk of the NDO_{HD} 2.1 system has been found to be acceptable by executive management.

Substantial Equivalence
The table below provides a detailed comparison of the NDŌHD High Definition Imaging System to the predicate device.

Item	Subject Device NDŌHD High Definition Imaging System, version 2.1	Predicate Device NDŌHD High Definition Imaging System (K131873)	Comparison
Intended Use	The NDŌHD system is intended for viewing, acquiring, recording, archiving and retrieving video and still images of endoscopic and fluoroscopic procedures.	The NDŌHD system is intended for viewing, acquiring, recording, archiving and retrieving video and still images of endoscopic and fluoroscopic procedures.	NDŌHD High Definition Imaging System Version 2.1 is identical to NDŌHD High Definition Imaging System (NDŌHD).
Indications for Use	The NDŌHD system is intended for viewing, acquiring, recording, archiving and retrieving video and still images of endoscopic and fluoroscopic procedures. The professionals or practitioners using this system would be medical doctors or clinicians such as speech pathologists. The device is a prescription device. The NDŌHD system is not intended to be used in an environment that requires sterilization.	The NDŌHD system is intended for viewing, acquiring, recording, archiving and retrieving video and still images of endoscopic and fluoroscopic procedures. The professionals or practitioners using this system would be medical doctors or clinicians such as speech pathologists. The device is a prescription device. The NDŌHD system is not intended to be used in an environment that requires sterilization.	NDŌHD High Definition Imaging System Version 2.1 is identical to NDŌHD High Definition Imaging System (NDŌHD).
Target Population	Medical doctors or clinicians such as speech pathologists	Medical doctors or clinicians such as speech pathologists	NDŌHD High Definition Imaging System Version 2.1 is identical to NDŌHD High Definition Imaging System (NDŌHD).
Computer	MacBook Pro 13-inch and 15-inch	MacBook Pro 15-inch	NDŌHD High Definition Imaging System Version 2.1 is equivalent to NDŌHD High Definition Imaging System (NDŌHD).

Item	Subject Device NDŌHD High Definition Imaging System, version 2.1	Predicate Device NDŌHD High Definition Imaging System (K131873)	Comparison
Display	Built-in computer display – 13-inch and 15-inch	Built-in computer display – 15-inch	NDŌHD High Definition Imaging System Version 2.1 is equivalent to NDŌHD High Definition Imaging System (NDŌHD).
Storage Medium	Non removable solid state drive (SSD)	Non removable hard drive	NDŌHD High Definition Imaging System Version 2.1 is equivalent to NDŌHD High Definition Imaging System (NDŌHD).
Operating System	macOS 10.14 +	macOS 10.8 +	NDŌHD High Definition Imaging System Version 2.1 is equivalent to NDŌHD High Definition Imaging System (NDŌHD), with the only difference being the version of the operating system. This difference does not affect the intended use or safety and effectiveness of the device.
Camera Coupler	C-Mount	C-Mount	NDŌHD High Definition Imaging System Version 2.1 is identical to NDŌHD High Definition Imaging System (NDŌHD).
Camera – Computer Cable	USB-3.0 USB C to USB Micro-B	Firewire	NDŌHD High Definition Imaging System Version 2.1 uses a different cable than the NDŌHD High Definition Imaging System. This

Item	Subject Device NDŌHD High Definition Imaging System, version 2.1	Predicate Device NDŌHD High Definition Imaging System (K131873)	Comparison
			difference does not affect the intended use or safety and effectiveness of the device.
Video Output Format	.mp4 H.264 Video	.mov H.264 Video	The video output format of the NDŌHD High Definition Imaging System Version 2.1 is different from the video output format used with the NDŌHD High Definition Imaging System. The difference in video format does not affect the intended use or safety and effectiveness of the device.
Still Image Output Format	.tiff Image	.tiff Image	NDŌHD High Definition Imaging System Version 2.1 is identical to NDŌHD High Definition Imaging System.
Camera Sensor Type	CMOS	CCD Progressive	The camera sensor type of the NDŌHD High Definition Imaging System Version 2.1 is different from the one used with the NDŌHD High Definition Imaging System. This difference does not affect the intended use or safety and effectiveness of the device.
Camera Frame Rate	203 fps (frames per second)	31 fps (frames per second)	The camera frame rate of the NDŌHD High Definition Imaging System

Item	Subject Device NDŌHD High Definition Imaging System, version 2.1	Predicate Device NDŌHD High Definition Imaging System (K131873)	Comparison
			Version 2.1 is different from the one used with the NDŌHD High Definition Imaging System. This difference does not affect the intended use or safety and effectiveness of the device.
Pixel Size	4.8 µm x 4.8 µm	4.65 µm x 4.65 µm	NDŌHD High Definition Imaging System Version 2.1 is equivalent to NDŌHD High Definition Imaging System.
Camera Bit Depth	10 bits	8 – 14 bits	NDŌHD High Definition Imaging System Version 2.1 is equivalent to NDŌHD High Definition Imaging System.
Camera Resolution (H x V)	1280 px x 1024 px	1032 px x 776 px	The camera resolution used in the NDŌHD High Definition Imaging System Version 2.1 is different from the one used with the NDŌHD High Definition Imaging System. This difference does not affect the intended use or safety and effectiveness of the device.
Power Consumption	3 W (Typical)	< 4 W	NDŌHD High Definition Imaging System Version 2.1 is equivalent to NDŌHD High Definition Imaging System.

Item	Subject Device NDŌHD High Definition Imaging System, version 2.1	Predicate Device NDŌHD High Definition Imaging System (K131873)	Comparison
Lossy Image Compression	Yes, H.264 compression	Yes, H.264 compression	NDŌHD High Definition Imaging System Version 2.1 is identical to High Definition Imaging System.
Power Source	Computer built in battery operated	Computer built in battery operated	NDŌHD High Definition Imaging System Version 2.1 is identical to power source of the NDŌHD High Definition Imaging System.
Software	NDŌHD Software is used to control the recording, playback, storage, retrieval, and live view of high definition video (.mp4), audio and images (.tiff) data.	NDŌHD Software is used to control the recording, playback, storage, retrieval, and live view of high definition video (.mov), audio and images (.tiff) data.	NDŌHD High Definition Imaging System Version 2.1 is equivalent to NDŌHD High Definition Imaging System.
Programming Language	Swift	Objective C	The programming language of the NDŌHD High Definition Imaging System Version 2.1 is different from the programming language of the NDŌHD High Definition Imaging System. This difference does not affect the intended use or safety and effectiveness of the device.

Testing
Software verification, system validation, and electrical safety testing have been completed according to FDA Guidance and Industry Standards as follows:

- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 11, 2002
- Guidance for the Submission of Premarket Notifications for Medical Image Management Devices, July 27, 2000
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices, September 9, 1999
- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 +A1:2012, Medical Electrical Equipment Part 1: General Requirements for Safety
- CAN/CSA C22.2 No. 60601-1:14
- IEC 60601-2-18:2009, Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-1-2:2014 4th Edition, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
- IEC 62304: 2006, Medical device software – Software life cycle processes

Substantial Equivalence Conclusions
In conclusion, the intended use for NDŌHD High Definition Imaging System, version 2.1 is the same as that of the NDŌHD High Definition Imaging System (K131873). The technological characteristics demonstrate that the NDŌHD High Definition Imaging System, version 2.1 is equivalent to the NDŌHD High Definition Imaging System, and the testing shows that the NDO_{HD} High Definition Imaging System, version 2.1 is substantially equivalent to the NDŌHD High Definition Imaging System (K131873) and assures that the NDŌHD High Definition Imaging System, version 2.1 is as safe and effective as the NDŌHD High Definition Imaging System (K131873).

Conclusion
The 510(k) Pre-market Notification for the NDŌHD High Definition Imaging System contains adequate information and data to determine that the Altaravision, Inc. NDŌHD High Definition Imaging System is as safe and effective as the legally marketed predicate device(s).