



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

April 6, 2017

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Huvitz Co., Ltd.  
% Mr. Dave Kim  
Medical Device Regulatory Affairs  
Mtech Group  
8310 Buffalo Speedway  
Houston, TX 77025

Re: K161829  
Trade/Device Name: Huvitz Imaging System  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture Archiving and Communications System  
Regulatory Class: Class II  
Product Code: NFJ  
Dated: March 2, 2017  
Received: March 6, 2017

Dear Mr. Kim:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

**Denise L. Hampton -S**

for Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose,  
and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K161829

Device Name

Huvitz Imaging System

Indications for Use (Describe)

Huvitz Imaging system (HIS-5000U) is intended for controlling digital imaging devices and for acceptance, transfer, display, storage and digital processing of documentation ophthalmic images and videos, acquired from a slit lamp camera through a direct connection to a PC or to multiple PCs via a local network.

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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## 510(k) Summary

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

**Date Prepared:** April 4, 2017  
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**Trade Name:** Huvitz Imaging System (HIS-5000U)  
**Common Name:** System, Image Management, Ophthalmic.  
**Regulation Number:** 21 CFR 892.2050  
**Regulation Name:** Picture archiving and communications system  
**Regulatory Class::** Class II  
**Product Code:** NFJ

**Predicate Device:** EyeSuite Imaging, K142423  
**Regulation Number:** 21 CFR 892.2050  
**Regulation Name:** Picture archiving and communications system  
**Regulatory Class::** Class II  
**Product Code:** NFJ

**Device Description:** Huvitz Imaging System (HIS-5000U) consists of slit lamp camera (HIS-5000U (10.0M), HIS-5000U(1.4M)), Communication Cable and Imaging Software (HIS-5000N). It is a digital imaging system with a high resolution digital camera and PC based patient diagnostic data management software intended for controlling digital imaging devices, acceptance, transfer, display, storage and digital processing of ophthalmic images including videos, acquired from a of a slit lamp camera through direct connection or network.

The imaging software (HIS-5000N) supports networking function to share patient information and examination images between multiple PCs existing on the local network or internet via TCP/IP protocol. Also, this version uses MS-SQL server solution as more reliable database, and includes additional HIS Server Management software to support to back up or restore patient and imaging data. HIS-5000N imaging system software is not able and

intended to provide any diagnosis but help the user to view the visible structures of the eye and store the findings.

**Intended Use:**

Huvitz Imaging system (HIS-5000U) is intended for controlling digital imaging devices and for acceptance, transfer, display, storage and digital processing of documentation ophthalmic images and videos, acquired from a slit lamp camera through a direct connection to a PC or to multiple PCs via a local network.

**Technological characteristics:**

Huvitz Imaging system (HIS-5000U) has been compared to the predicated device. The following attachment shows differences and similarities among the device.

**Non-clinical and clinical tests:**

Performance testing was conducted on the Huvitz Imaging System (HIS-5000U). System and supported instrument testing was completed based on product specifications and hazard effects determined from the risk analysis. The Huvitz Imaging System (HIS-5000U) performed as intended and is deemed substantially equivalent to and comparable to the predicate device, an ophthalmic patient database device.

Also, the following tests have been conducted to validate the performance of Huvitz Imaging System (HIS-5000U).

1) Camera Image capture, 2) Saving image file, 3) Adjust color of capture image, 4) Measurement of figures, 5) Camera resolution & data transfer speed as per the manufacturer's performance report.

No clinical test has been conducted.

**Conclusions:**

Based on non-clinical tests, the subject device, Huvitz Imaging System (HIS-5000U) introduces no new concern for safety and effectiveness. Therefore it is the sponsor's opinion that Huvitz Imaging System (HIS-5000U) is substantially equivalent to the predicate device.

**Attachment****< Comparison Table of Technical Characteristics >**

| <b>Characteristic</b>                              | <b>Subject Device</b><br>Huvitz Imaging System<br>HIS-5000U                                                                                                                                                                                                                                                             | <b>Predicate Device</b><br>Haag-Streit, EyeSuit Imaging                                                                                                                                                                                                                                                                                                                                                                                                                      |
|----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>510(k) number</b>                               | New (K161829)                                                                                                                                                                                                                                                                                                           | K142423                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Manufacturer</b>                                | Huvitz Co.,Ltd                                                                                                                                                                                                                                                                                                          | Haag-Streit                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Device Name</b>                                 | Huvitz Imaging System<br>HIS-5000U                                                                                                                                                                                                                                                                                      | EyeSuit Imaging                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Intended Use</b>                                | Huvitz Imaging system (HIS-5000U) is intended for controlling digital imaging devices and for acceptance, transfer, display, storage and digital processing of documentation ophthalmic images and videos, acquired from a slit lamp camera through a direct connection to a PC or to multiple PCs via a local network. | EyeSuit Imaging is a software program intended for use for controlling digital imaging devices and for acceptance, transfer, display, storage and digital processing of documentational ophthalmic images and videos, acquired from computerized diagnostic instruments, through direct connection or through networks.<br>EyeSuite Basic is a patient and examination management system, acting as a base and communication platform for other EyeSuite software components |
| <b>Memory</b>                                      | 2,048MB                                                                                                                                                                                                                                                                                                                 | 1GByte                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Graphic Card</b>                                | 512MB                                                                                                                                                                                                                                                                                                                   | 120MB                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Operating System</b>                            | Window 7                                                                                                                                                                                                                                                                                                                | Windows Vista, Window XP                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Interface</b>                                   | USB 2.0                                                                                                                                                                                                                                                                                                                 | DICOM PACS                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Monitor resolution</b>                          | 1920 x 1080                                                                                                                                                                                                                                                                                                             | 1280 x 800                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| How to store patient data and diagnostic documents | Be comprised of a local database to store patient data and diagnostic documents                                                                                                                                                                                                                                         | Be comprised of a central database to store patient data and diagnostic documents                                                                                                                                                                                                                                                                                                                                                                                            |
| Type of images and video format                    | JPEG                                                                                                                                                                                                                                                                                                                    | JPEG, TIFF, MJPEG                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Ability to control camera                          | Be capable of controlling supported camera system and                                                                                                                                                                                                                                                                   | Be capable of controlling supported camera systems and                                                                                                                                                                                                                                                                                                                                                                                                                       |

| <b>Characteristic</b>                                                                                                  | <b>Subject Device</b><br>Huvitz Imaging System<br>HIS-5000U                                                                                                                                                                                      | <b>Predicate Device</b><br>Haag-Streit, EyeSuit Imaging                                                                       |
|------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| systems and exposure parameters like signal gain, exposure time or white balance (by default or an option)             | exposure parameters like signal gain, exposure time or white balance.                                                                                                                                                                            | exposure parameters like signal gain, exposure time or white balance                                                          |
| Ability to provide the management, storage and processing and display of patient, diagnostic video and image data      | USB Camera has unique power requirement that varies on image resolution and data bandwidth needed to transport image data                                                                                                                        | Provide the management, storage and processing and display of patient, diagnostic, video and image data                       |
| Type of system that provide a software application (client) to view or modify the stored data in the database (server) | Software should be installed in a computer using an installer file. After the software and camera driver installation, HIS-5000U program can check patient image data and current database information on a local computer.                      | Client-server systems that provide a software application (client) to view or modify the stored data in the database (server) |
| Functions to add test notes to medical records                                                                         | Diagnosis management can add or edit diagnostic information.                                                                                                                                                                                     | Provide a function to add text notes to medical records                                                                       |
| Function to highlight features in images                                                                               | User can select a thumbnail image by clicking it, which is highlighted as bright color, and it is able to select several images from different exams of the same patient. The selections are cleared when the processing on image are completed. | Provide a function to highlight features in images                                                                            |
| Function to enhance image brightness, contrast and sharpness                                                           | Provide functions to enhance image brightness, contrast and sharpness.                                                                                                                                                                           | Provide functions to enhance image brightness, contrast and sharpness                                                         |

| <b>Characteristic</b>                                                      | <b>Subject Device</b><br>Huvitz Imaging System<br>HIS-5000U                                                                                             | <b>Predicate Device</b><br>Haag-Streit, EyeSut Imaging                           |
|----------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Function to measure pixels or mm,                                          | Function to measure pixels and mm                                                                                                                       | Provides the measurement functionality in pixels and measurements in mm          |
| Function to search to retrieve medical records lined to a specific patient | All patient data is stored in a database file, and a search function can retrieve patient database transaction history stored in the Database Log File. | a search function to retrieve medical records linked to a specific patient       |
| Function to export and import data                                         | Include a function to export and import data                                                                                                            | Include a function to export and import data                                     |
| Function to print out the stored data                                      | Can produce printouts of the stored data.                                                                                                               | Can produce printouts of the stored data                                         |
| Function to compare images by displaying images side by side               | Function to compare images by displaying images side by side<br>More than two images can be selected from Thumbnail List for comparison.                | Comprise an image compare function by displaying images side by side             |
| Function to connect to LAN and have DICOM interface                        | Can connect to LAN but No DICOM interface                                                                                                               | Can connect to LAN and have DICOM interface (by default or as a separate option) |