



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

AlgoMedica  
% Christopher J. Devine, Ph.D.  
President  
Devine Guidance International, Inc.  
4730 South Fort Apache Road, Suite 300  
LAS VEGAS NV 89147

September, 19, 2016

Re: K161625  
Trade/Device Name: PixelShine  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: August 19, 2016  
Received: August 24, 2016

Dear Dr. Devine:

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 yours,



For

Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K161625

Device Name

PixelShine

Indications for Use (Describe)

The AlgoMedica PixelShine System is intended for networking, communication, processing and enhancement of CT images in DICOM format. It is specifically indicated for assisting professional radiologists and specialists in reaching their own diagnosis. The device processing is not effective for lesion, mass or abnormalities of sizes less than 3.0 mm. The AlgoMedica PixelShine is not intended for use with or for diagnostic interpretation of mammography images.

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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## Section Five (5) - 510(k) Summary

### 510(k) SUMMARY

[As Required by 21 CFR 807.92(c)]

**Submitter's Name & Address:** AlgoMedica  
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**Contact Person:** Christopher J. Devine, Ph.D.  
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chris.devine@devineguidanceinternaional.com

**Date Summary Prepared:** June 06, 2016

**Device Name:** Trade/Proprietary Name – PixelShine

Common/Usual Name – System, Image Processing,  
Radiological

Classification Name – 892.2050 - Picture archiving and  
communications system

**Classification:** Class II

**Product Code:** LLZ

**Regulation Number:** 892.2050

**Predicate Device:** Medic Vision Brain Technologies, LTD – SafeCT  
(K100372)

## **Previous FDA Submissions & Clearances**

AlgoMedica has no previous regulatory submissions with the FDA.

## **Device Description**

PixelShine is a medical imaging application that can receive, transfer and perform noise reduction of CT DICOM images over a user network. Received images are processed by the PixelShine to reduce noise, thereby enhancing image quality.

## **Intended Use**

The AlgoMedica PixelShine is intended for networking, communication, processing and enhancement of CT images in DICOM format. It is specifically indicated for assisting professional radiologists and specialists in reaching their own diagnosis. The device processing is not effective for lesion, mass or abnormalities of sizes less than 3 mm The AlgoMedica PixelShine is not intended for use with or for diagnostic interpretation of Mammography images.

## **Prescriptive Statement**

Caution: Federal law restricts this device to sale by or on the order of a physician.

## **Safety & Effectiveness**

The PixelShine has been designed, verified and validated in compliance with 21 CFR, Part 820.30 requirements. The device has been designed to meet the requirements associated with EN ISO 14971:2012 (risk management). The PixelShine performance has been validated through the use of phantoms and the comparison of collected image data to ascertain image quality. The results of the performance testing demonstrate the safety and effectiveness of the PixelShine.

## **Technological Characteristics/Principles of Operation**

PixelShine is a medical imaging application that runs on an AlgoMedica-specified, customer's Off-the-Shelf Personal Computer (PC) and performs noise reduction processing and transfer of CT DICOM images over a user network. Once installed by AlgoMedica trained personnel, PixelShine operates independently, without the need for I/O devices such as mouse and keyboard. It is indicated for assisting radiologists and other medical specialists in arriving at their own diagnosis. The technology for noise reduction is based on a non-linear filter, which reduces noise in the original image. Figure 5.1 depicts a typical deployment of the PixelShine at a customer site.

### ***PixelShine Components and Hardware Requirements***

The following components and hardware requirements are an integral part of the PixelShine:

- PixelShine Version 1 Software Package;
- Linux Operating System;
- DICOM Server software installed on PixelShine provides all DICOM communications;  
and
- AlgoMedica specified off-the-shelf PC Hardware (*minimum Requirements*) containing:
  - Intel CPU with 4 cores;
  - 16GB RAM;
  - 500GB hard drive; and
  - Two - 1 Gigabit Ethernet ports

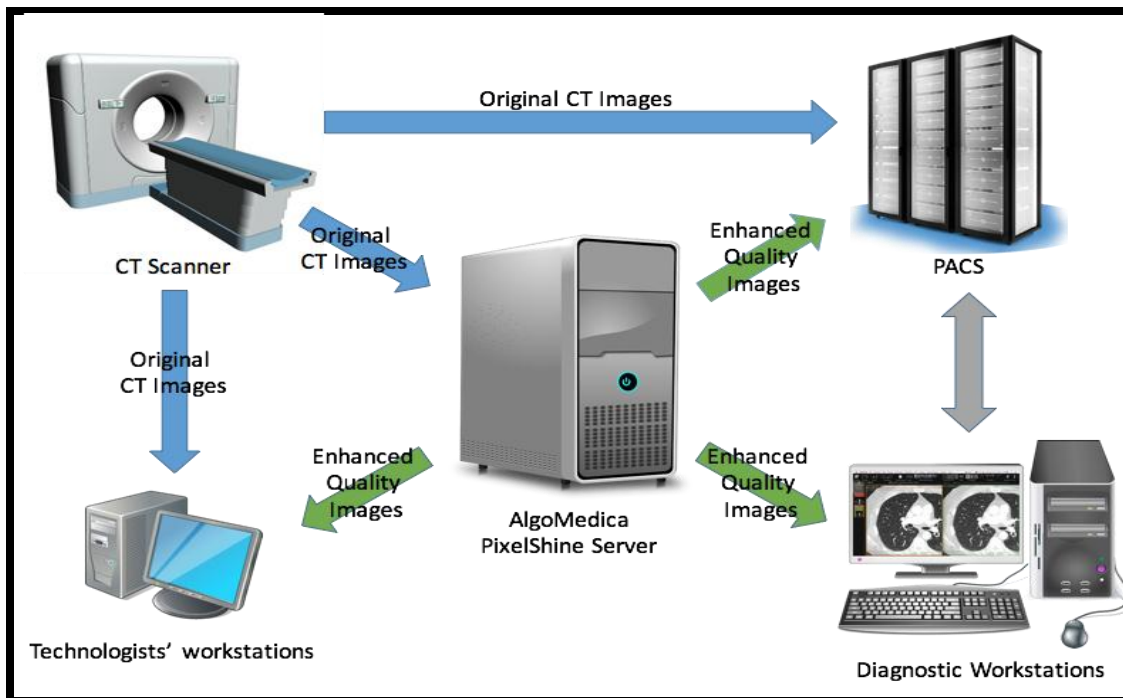
### ***PixelShine Functional Capabilities***

The following functions are associated with performance of the PixelShine (*reference*

*Figure 5.1*):

- Operates in a network server mode environment;
- Functions as a DICOM device on the user network;
- Capable of receiving CT images from different DICOM devices over the network;
- Capable of receiving images from multiple DICOM devices;
- Processes the CT images upon receiving them from a DICOM device; and
- Sends the processed CT image to one or more destination DICOM devices.

**Figure 5.1 – Pixel Shine Functional Block Diagram (deployment scenario)**



*Note: PixelShine receives original CT images, processes them and routes the enhanced quality images to a PACS system. As in current practice, the technologist is able to view both the original and the processed images on his workstation and take appropriate action as necessary. Both the original and processed images can be stored on the PACS server.*

### **Summary of Non-Clinical Performance and Safety Testing**

The following non-clinical performance testing was performed with satisfactory results. All of the testing was performed with the use of an approved testing protocol. Details of each test, including protocols and reports are located in Appendix E of this 510(k).

- Unit Integration Testing – Pass;
- PixelShine System-Level-Testing – Pass;
- PixelShine Verification Testing – Pass; and
- PixelShine Validation Testing - Pass.

### **Substantial Equivalence Discussion**

#### ***Medic Vision Brain Technologies Ltd. – SafeCT (K100372)***

The PixelShine is substantially equivalent to the devices previously cleared by FDA (reference 510(k) – K100372). AlgoMedica claims this equivalence because the proposed device has an equivalent intended use, theory of operation, operating principals, and operational specifications as compared to the predicate device. The similarities and differences between the proposed and predicate device have been delineated within a comparison chart which has been included in Section 12 of this 510(k) submission.

### **Conclusion Statement**

The AlgoMedica PixelShine has the same intended use as the predicate device. Any technological changes to the device do not raise new questions of safety or effectiveness. Performance testing, along with verification and validation activities demonstrate that the AlgoMedica PixelShine is as safe and effective, and performs as well as the predicate device. Therefore, the AlgoMedica PixelShine can be considered substantially equivalent to the predicate device.