K070954

# 510(k) SUMMARY

APR 20 2007

## General Information

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|---|---|
| Submitted by: | Raster Builders, Inc.<br>650 South Eliseo Drive<br>Greenbrae, CA 94904<br><br>Phone: (800) 925-2134 |
| Contact Person: | Eric Chasanoff<br>650 South Eliseo Drive<br>Greenbrae, CA 94904<br><br>Phone: (800) 925-2134 |
| Date Prepared: | February 23, 2007 |

## Device Information

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|---|---|
| Trade Name: | PatientGallery Imaging Software |
| Common Name: | Picture archiving and communications system |
| Classification: | Class II |
| Classification Name: | System, Image Processing, Radiological |
| Reference: | 21 CFR 892.2050 |

## Predicate Device

| **Manufacturer 510(k) No.** | **Product Name** |
|---|---|
| Televere Systems K061035 | TigerView Professional |

## Device Description

PatientGallery Imaging Software is a Windows-based image management database, or system used primarily by Dentists for the indications of acquiring, archiving, displaying, editing, printing, emailing, and importing or exporting digital images.

The database is organized like a file cabinet by patient. Each patient folder accommodates grayscale and color images which may also include textual and graphic notes and annotations. Images may be assembled into layouts which can be customized as required. Optional modules provide editing and viewing functions.

Image acquisition from x-ray sensors, intra-oral video cameras, digital cameras and flatbed scanners can be distributed among several workstations. The software provides direct interfaces to many industry standard devices through OEM toolkits. PatientGallery Imaging Software uses standard Windows peer-to-peer networking. By default, images are stored in the native format provided by the hardware manufacturers. PatientGallery Imaging Software may be invoked by other practice management applications so that specific patient information is accessed.

**Intended Use**

PatientGallery Imaging Software will be used primarily by Dentists for the indications of acquiring, archiving, displaying, editing, printing, emailing, and importing or exporting digital images.

**Safety Information**

A Hazard Analysis was performed for the PatientGallery Imaging Software, which led to the development of Software Requirement Specifications (SRS). The SRS was used to develop a Verification & Validation (V&V) plan executed through a series of Test Cases. The V&V testing was passed, demonstrating that the PatientGallery Imaging Software performs as indicated.

**Conclusion**

The information contained in this Pre-market Notification is sufficient to demonstrate that the PatientGallery Imaging Software functions as described, and is substantially equivalent to the TigerView Professional software manufactured by Televere Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Raster Builders, Inc.
% Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Underwriters Laboratories, Inc.
455 East Trimble Road
SAN JOSE CA 95131

APR 20 2007

Re: K070954
Trade/Device Name: Patient Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 4, 2007
Received: April 5, 2007

Dear Mr. Christensen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

**510(k) Number:** ~~None~~ K070954

**Name of Device:** PatientGallery Imaging Software

**Indications for Use:**

PatientGallery is a Windows-based image management system indicated for use primarily by dentists to acquire, archive, display, edit, print, email, and import/export digital images.

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|---|---|---|
| Prescription Use ___X___ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070954