K101654

American Dental Partners, Inc.
401 Edgewater place
Suite 430
Wakefield, MA 01880

NOV 10 2010

510(k) Summary
IMPROVIS® Imaging System

The following information is presented as required by 21 C.F.R. § 807.92:

Date Prepared:	September 29, 2010
Submitter:	American Dental Partners, Inc. 401 Edgewater Pl., Ste. 430 Wakefield, MA 01880-6225
Establishment Registration Number:	To be obtained
Manufacturing Site:	American Dental Partners, Inc. 3000 Bethesda Place, Suite 501 Winston-Salem, NC 27103 Phone: 336-765-3900
Contact Person:	Timothy Rodenberger General Counsel American Dental Partners, Inc. Tel: 781-213-0255 Fax: 781-224-4216 Email: TRodenberger@amdpi.com
Device Trade Name:	IMPROVIS® Imaging System
Common Name:	Dental Imaging Software
Device Classification:	Picture Archiving and Communications System
Product Code:	LLZ
Regulation:	21 C.F.R. § 892.2050
Device Classification:	Class II

Predicate Devices:

Televere Systems	Visix Imaging	K082623
Televere Systems	TigerView Professional	K061035

Device Description

Improvis Imaging is a software package that allows dental clinicians to acquire images from standard dental imaging devices and commercially available scanners, digital cameras and intra-oral cameras. It is designed to be used as an imaging database for storage and organization of patient digital images and radiographs. Once acquired, images can be enhanced for viewing by applying image processing functions which include resizing, rotating, embossing and sharpening of images. All images are compressed using lossless compression and stored in a shared relational database.

The Improvis software interacts with the medical device software drivers, not the medical devices themselves. This interaction allows the computer system to acquire images captured via webcams, intraoral video cameras, panoramic x-rays, and other solid state sensors. These images are digitized by the outside vendor supplied medical devices, and then communicated via Improvis to the patient record. Once the images have been received by the system, they are embedded within the patient's dental record and can be accessed from any associated practice location.

Radiographic images are compressed via a lossless system and can be manipulated and enhanced to suit the dental care provider's needs. Non-diagnostic images, such as scanned documents, may be compressed using non-lossless methods which optimize image quality and storage requirements. Original compressed images are stored prior to application of any image processing algorithms.

Image processing by Improvis Imaging utilizes industry standard algorithms that do not result in the alteration of an image's or radiograph's content and will not introduce false data or modification into the acquired image. Improvis Imaging does not control the x-ray taking system and does not generate x-ray images directly from the physical device, but does provide the tools that permit the user to enhance images for diagnostic purposes.

Improvis Imaging is a three tier application consisting of user interface, business objects (which provide communication between the user interface and database tiers), and database. The top two tiers of the program are written in Microsoft Visual Studio .NET C#, while the database components are written in Microsoft T-SQL. Improvis Imaging is a Microsoft Windows Forms (non-browser based) 32 bit application designed to run on Windows-compatible personal computers running the Microsoft Windows XP (or higher) operating system. Imaging processing functions are provided through the integration of a third party software development toolkit from Lead Technologies, Inc.

Improvis Imaging is designed for use in a client-server environment in which the user interface portion of the application runs on an individual user's computer workstation as a Windows

executable application. The Improvis Imaging shared database is installed on a single or clustered server running Microsoft SQL Server. The workstations and server are connected by a network using Microsoft Windows IP protocols. The application is designed for use in a Microsoft Windows Active Directory domain for authentication and access control, but can also run in non-Active Directory workgroups using internal Improvis access control.

Improvis Imaging is not compliant with DICOM standards.

Intended Use

Improvis Imaging is a Windows-based software package that allows dental clinicians to acquire images from standard dental imaging devices and commercially available scanners, digital cameras and intra-oral cameras. It is designed to be used as an imaging database for storage and organization of patient digital images and radiographs. Features include resizing, rotating, embossing and sharpening of images. Intended users of this system are trained professionals, including but not limited to dentists, hygienists and clinical assistants.

Narrative Description of Substantial Equivalence:

The Improvis Imaging system is substantially equivalent to the predicate devices identified above. In particular, Improvis Imaging has the same intended use and similar technological features as the predicate devices. Like Visix Imaging and TigerView Professional, Improvis Imaging is a software application that supports the acquisition, viewing and editing of images and data from an imaging source. Images can be acquired from document scanners, intraoral video cameras, web cameras, digital cameras, and radiographic systems. Images are associated with patient records and presented using standard computer workstations and displays. The software is intended for use by dental professionals for diagnostic purposes, case documentation, and patient education. Users can overlay annotations on images, as well as calibrate and measure images. Methods such as brightness and contrast adjustment, sharpening, colorization, and reorientation are provided to allow images to be enhanced for optimal viewing. Images can also be printed and exported.

A comparison of the characteristics of the current device and the predicate devices is set forth in the charts below.

Device Comparison

Table 1. Device Comparison

Comparison Areas	IMPROVIS Imaging	Visix Imaging	TigerView Professional
Intended Use	Acquiring, viewing, editing and storage of dental radiographs and related patient image records	Same	Same
Intended Users	Trained dental professional	Same	Same
DICOM Compatible	No	Optional	Optional
Operating System	Microsoft Windows XP or higher 32 and 64 bit OS	Microsoft Windows 2000 or higher 32 bit OS	Microsoft Windows 98 or higher 32 bit OS
Network	Ethernet IP 100 mbps or greater	Same	Same
Monitor	800 x 600 or greater	1024 x 768 or greater	800 x 600 or greater
User Interaction/Input	Keyboard/Mouse	Same	Same
CPU	2 GHz Pentium or higher	Same	Same
RAM	1 GB or higher	Same	Same
Multi-User	Yes	Same	Same
Import/Export Images	Yes (BMP, TIFF, JPG)	Yes (TIFF, JPG)	Yes (TIFF, JPG)
Acquisition Devices	Sensor Camera Scanner File Import	Same	Same
Imaging Interfaces	Microsoft DirectX Version 9.0 and higher TWAIN 2.0 and higher	Proprietary DirectX TWAIN	Proprietary DirectX TWAIN
Image Organization	Create Series Move Images Create Series Template	Mount Images Move within Mount Create a Mount	Mount Images Move within Mount Create a Mount
Image Search Available	Yes	Same	Same
Image Storage	Original data unaltered Lossless compression of radiographic images Full history of enhancements recorded with each image	Original data unaltered Lossless/lossy compression History of operations	Original data unaltered Lossless/lossy compression History of operations
Database Storage	Microsoft SQL Server database	File System	File System
Database Software	Microsoft SQL Server 2005 or higher	File System	File System

Comparison Areas	IMPROVIS Imaging	Visix Imaging	TigerView Professional
Image Viewing	Zoom In and Out Full Screen Scale to 100% Rotate 90 or 180 degrees Flip Left to Right Flip Top to Bottom Rotate 0 Degrees	Zoom In and Out Full Screen Reset Zoom Rotate 90° or 180° Flip Left to Right Flip Top to Bottom Reset Orientation	Zoom In and Out Full Screen Reset Zoom Rotate 90° or 180° Flip Left to Right Flip Top to Bottom Reset Orientation
Image Measurement	Line Angle Calibrate Line Color Show/Hide	Line Angle Calibrate Line Color Show/Hide	Line Angle Calibrate Line Color Show/Hide
Image Annotation	Line Free Line Circle Rectangle Arrows Text Color Width Show/Hide	Line Freehand Circle Square Arrows Text Color Width Show/Hide	Line Freehand Circle Square Arrows Text Color Width Show/Hide
Image Operations	Magnifier Print Negative Colorize Emboss Sharpen Original Image Brightness Contrast Gamma	Magnifying Glass Print Negate Colorize Pseudo 3D Sharpen Edge Original Image Brightness Contrast Gray Shift (Gamma)	Magnifying Glass Print Negate Colorize Pseudo 3D Sharpen Edge Original Image Brightness Contrast Gray Shift (Gamma)
Security	Login, admin, and feature access	Login and admin	Login and admin

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

American Dental Partners, Inc.
% Mr. Timothy Rodenberger
General Counsel
401 Edgewater Place, Suite 430
WAKEFIELD MA 01880-6225

NOV 10 2010

Re: K101654
Trade/Device Name: Improvis® Imaging System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 29, 2010
Received: September 29, 2010

Dear Mr. Rodenberger:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101654

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Device Name: Improvis® Imaging System

Indications for Use:

Improvis Imaging is a Windows-based software package that allows dental clinicians to acquire images from standard dental imaging devices and commercially available scanners, digital cameras and intra-oral cameras. It is designed to be used as an imaging database for storage and organization of patient digital images and radiographs. Features include resizing, rotating, embossing and sharpening of images.

Improvis Imaging is written using three programming languages (C++, C#, TSQL) and is designed to work with standard personal computers capable of running Windows 2000 or higher.

Intended users of this system are trained professionals, including but not limited to dentists, hygienists and clinical assistants.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)