K122065

510(k) Summary

SYBRON DENTAL SPECIALTIES

FEB 8 2013

Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Avenue
Orange, California 92867
(714) 516-7602 - Phone
(714) 516-7472 - Facsimile
Wendy Garman - Contact Person

Date Summary Prepared: February 2013

Device Name:

- Trade Name - Digital Impression System for Orthodontic Use
- Common Name - Intraoral Imaging System
- Classification Name - Optical Impression Systems for CAD/CAM, per 21 CFR § 872.3661
- Product Codes - Optical Impression System, Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations (NOF)

Devices for Which Substantial Equivalence is Claimed:

- *3M Unitek Lava Chairside Oral Scanner, Brontes Technologies, Inc.* K081961

Device Description:

The *Digital Impression System for Orthodontic Use* (DIS) is a handheld intraoral 3D imager intended for use inside the human oral cavity to digitally capture the three-dimensional topography of teeth, gingiva, and/or palate in clinical settings. It is intended to replace traditional cast impressions which are the current standard for recording dental and orthodontic features of patients undergoing orthodontic treatment. The system is intended to be used by orthodontists and orthodontic assistants in an orthodontic office environment. The system consists of a handheld wand connected to a computer which is housed in a base unit. The computer contains proprietary software to acquire, process, and store the digital 3D image data. Patient information is entered into the software using a touch screen monitor connected to the computer. To capture a 3D image of the patient's dental arch and/or bite, the operator

moves the wand over the surface of the teeth to be scanned. A video camera inside the wand captures images of the teeth surfaces. Algorithms in the software process these images into a 3D image and display the 3D image on the computer monitor in real time. The software also saves the 3D image data and identifying patient information to be used by orthodontic manufacturers to design and manufacture customized orthodontic appliances.

Indications for Use:

The Digital Impression System for Orthodontic Use is an optical impression system intended for use by dental professionals to record the topographical characteristics of teeth, gingiva, and/or palate. The Digital Impression System is intended for use in conjunction with the production of orthodontic appliances.

Summary of Technological Characteristics:

The Digital Impression System for Orthodontic Use is substantially equivalent to another legally marketed device in the United States. *The Digital Impression System for Orthodontic Use* functions in a manner similar to and is intended for the same use as *3M Unitek Lava Chairside Oral Scanner* that is currently marketed by *Brontes Technologies, Inc.*

Features	**Digital Impression System for Orthodontic Use**	***3M Unitek Lava Chairside Oral Scanner***
Indications for Use	*The Digital Impression System for Orthodontic Use* is an optical impression system intended for use by dental professionals to record the topographical characteristics of teeth, gingiva, and/or palate. The Digital Impression System is intended for use in conjunction with the production of orthodontic appliances.	The 3M Unitek Lava Chairside Oral Scanner is an optical impression system (CAD/CAM) used to record the topographical characteristics of teeth. Data generated from the 3M Unitek Lava Chairside Oral Scanner may be used in conjunction with the production of orthodontic appliances, retainers and accessories.
Target users	Dental Professionals trained in orthodontics	Dental Professionals trained in orthodontics
Where used	Dental offices, used at dental chair	Dental offices, used at dental chair
Anatomical Sites	Upper and lower arches of teeth, left and right bite	Upper and lower arches of teeth, left and right bite
Features	Digital Impression System for Orthodontic Use	*3M Unitek Lava Chairside Oral Scanner*
Technique to	Interferometry measurement of	Stereoscopic measurement of

Produce 3D Images	video camera images	video camera images
Light used for illumination	Blue (405 nm)	Blue (405 nm)
Light Source	Diode (laser)	Diode (light emitting)
Tooth Coating	None	Titanium dioxide powder
Components	Handheld imaging wand containing a high accuracy video camera	Handheld imaging wand containing a high accuracy video camera
	Computer mounted in housing that can be moved from room to room	Computer mounted in housing that can be moved from room to room
	Cable connecting wand with computer	Cable connecting wand with computer
	Touch screen monitor	Touch screen monitor
Key Characteristics	Handheld wand is moved over the teeth to acquire 3D images	Handheld wand is moved over the teeth to acquire 3D images
	Real-time display of 3D images while patient is being imaged	Real-time display of 3D images while patient is being imaged
Device Output	Output is a software file that can be used as input to CAD/CAM dental processes	Output is a software file that can be used as input to CAD/CAM dental processes
Patient Contact Areas	Cheek, tongue, lips, teeth, palate	Cheek, tongue, lips, teeth, palate
Patient Contact Areas; Cross-contamination Control	Wand tip is single patient/single use disposable	Wand tip must be sterilized between patients
Checks of software and hardware function	Scan of verification target	Scan of verification target

Non-Clinical Test Data:

Biocompatibility studies (Cytotoxicity, Irritation and Sensitization) have been completed on the disposable wand tip included in the *Digital Impression System for Orthodontic Use* product.

3D topographical files were created by the *Digital Impression System for Orthodontic Use* and compared to files derived from, digitized polyvinylsiloxane (PVS) traditional impressions. Test results confirmed that digital impressions generated by the *Digital Impression System for Orthodontic Use* are substantially equivalent to PVS impressions made by traditional means.

Additionally, the *Digital Impression System for Orthodontic Use* software has been successfully validated to confirm the performance of the device.

Clinical Test Data:

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the biocompatibility studies, similar technological characteristics to the predicate device, comparison between 3D topographical files created by the *Digital Impression System for Orthodontic Use* and files created from digitized PVS impressions and successful validation of the *Digital Impression System for Orthodontic Use* software, the performance of the *Digital Impression System for Orthodontic Use* is deemed to be substantially equivalent to *3M Unitek Lava Chairside Oral Scanner.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 8, 2013

Ormco Corporation
C/O Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
ORANGE CA 92867

Re: K122065
Trade/Device Name: Digital Impression System for Orthodontic Use
Regulation Number: 21 CFR 872.3661
Regulation Name: Optical Impression Systems for CAD/CAM
Regulatory Class: II
Product Code: NOF
Dated: February 1, 2013
Received: February 5, 2013

Dear Ms. Garman:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122065

Indications for Use

510(k) Number (if known): K122065

Device Name: *Digital Impression System for Orthodontic Use*

Indications For Use:

The *Digital Impression System for Orthodontic Use* is an optical impression system intended for use by dental professionals to record the topographical characteristics of teeth, gingiva and/or palate. The Digital Impression System is intended for use in conjunction with the production of orthodontic appliances.

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 Device Evaluation (ODE)

Andrew I. Steen
2013.02.07 15:52:22 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122065