k122467

3M ESPE
Dental Products

3M Center
St. Paul, MN 55144-1000
651 733 1110

NOV 2 0 2012

3M ESPE

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter..... 3M Company
3M ESPE Dental Products
3M Center, 275-2W-08
2510 Conway Avenue
St. Paul, MN 55144-1000 USA

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Date Summary was Prepared.....November 16, 2012

Trade Name.....3M True Definition Scanner (Model G5)

Common Name(s).....Intra-Oral Scanner

Recommended Classification.....Optical Impression Systems for CAD/CAM, Class II device, (21 CFR § 872.3661, Product Code: NOF)

Predicate Devices:
3M™ ESPE™ Lava Chairside Oral Scanner (C.O.S.), K073199
3M™ Unitek™ Lava Chairside Oral Scanner (C.O.S.), K081961

Description of Device:
The 3M True Definition Scanner is a digital impression generating system consisting of a computer system on a mobile cart, a lightweight scanning wand, and embedded software (including firmware). Accessory items include a contrast powder to be applied to the patient's teeth and/or oral anatomy and a battery powered powder sprayer.

The computer system consists of a commercial off-the-shelf personal computer (PC) and a touch screen monitor.

The scanning wand is a hand held optical device that captures high-resolution video images, in real time, as the patient is being scanned. The wand contains an optical system comprised of low intensity LED's, a light sensor, a lens and supporting electronics. The wand is connected to the cart via a high speed data transfer cable. The wand is designed to be easily maneuvered inside the patient's mouth and captures video imagery at 20 frames per second. Those images are converted to 3D data sets and displayed in real time.

The software contains high-speed image processing algorithms, real-time modeling, case management, and archival functionality.

3M True Definition Scanner facilitates a digital workflow which reduces or eliminates many steps traditionally required by the dentist and lab, including tray selection, plaster pouring, material dispensing, base & pin, material setting, die cutting, trimming, articulation, packaging and shipping.

Indications for Use:

3M True Definition Scanner is an optical impression system used to record the topographical characteristics of the dentition and/or full arch and preparation areas (including features such as implant scan locator fixtures, braces, brackets, etc.). In addition it can record the topographical characteristics of the oral anatomy (such as soft tissue, gingivae and palate).

The three dimensional (3D) model generated from the scan may be further used for the design and manufacturing of dental restorations including implant supported prostheses and partial frameworks, and can be used to design and manufacture physical models of the teeth.

It may also be used in conjunction with production of orthodontic appliances, retainers and accessories.

Electrical Safety/Electromagnetic Compatibility (EMC)

3M ESPE provided data in the 510(k) to demonstrate the device meets the requirements of ANSI/AAMI ES60601-1: 2005 (i.e., IEC 60601-1: 2005), *Medical electrical equipment – Part1: General requirements for basic safety and essential performance*, IEC60601-1:1998 + A1:1992 + A1:1995, *Medical electrical equipment – Part 1: General requirements for safety*, and IEC 60601-1-2: 2007, *Medical Electrical Equipment –Part 1: General Requirements for Safety: Collateral Standard: Electromagnetic Compatibility Requirements and Tests.*

In addition, information was provided in the 510(k) to demonstrate the 3M True Definition Scanner meets the requirements of IEC62471:2006, *Photobiological safety of lamps and lamp systems.*

3M concludes that the 3M True Definition Scanner is safe for its intended use/indications for use.

Biocompatibility

3M provided data in this 510(k) to demonstrate the 3M True Definition Scanner meets the requirements of relevant parts of ISO10993-1(2009), *Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing within a Risk Management Process* and that the device meets the requirements of ISO 7405: 2008, *Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry.*

Non-Clinical Testing

3M successfully performed software verification and validation activities including testing of the device's accuracy, case processing, data management, fault management, network access and remote service, patient, doctor and prescription management, scanning operations and workflows to laboratories and mills. Results of accuracy testing are shown in the Substantial Equivalence summary below.

Substantial Equivalence:

3M ESPE's evaluation of the substantial equivalence of the True Definition Scanner to the Lava C.O.S. predicates was based on a comparison of device classification, intended use and indications for use, contraindications, labeling, technological attributes, accuracy, and accessories. 3M also compared risks and End-of Useful Life for both devices.

Comparison of Intended Use/Indications for Use/Contraindications			
Feature	**3M True Definition Scanner (FDA 510(k)# K122467)**	**3M ESPE Lava C.O.S. (FDA 510(k)# K073199)**	**3M Unitek Lava C.O.S. (FDA 510(k)# K081961)**
Procode	NOF	NOF	NOF
Classification	Optical Impression System for CAD/CAM 21 CFR §872.3661	Optical Impression System for CAD/CAM 21 CFR §872.3661	Optical Impression System for CAD/CAM 21 CFR §872.3661
Indications for Use	3M True Definition Scanner is an optical impression system used to record the topographical characteristics of the dentition and/or full arch and preparation areas (including items such as implant scan locator fixtures, braces, brackets, etc.). In addition, it can record the topological characteristics of the oral anatomy (such as soft tissue, gingivae, and palate). The three dimensional (3D) model generated from the scan may be further used for the design and manufacturing of dental restorations including implant supported prostheses and partial frameworks, and can be used to design and manufacture physical models of the teeth. It may also be used in conjunction with the production of orthodontic appliances, retainers and accessories.	The 3M ESPE Lava Chairside Oral Scanner (C.O.S.) is an optical impression system (CAD/CAM) used to record the topographical characteristics of teeth.	The 3M Unitek Lava Chairside Oral Scanner (C.O.S.) 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.
Contra-indications	None	None	None

Technological Comparison			
Item	**3M True Definition Scanner (K122467)**	**Lava C.O.S. (510(k)# K073199)**	**Lava C.O.S. (510(k)# K081961)**
Operating System	Fedora 15 (Linux)	Custom Gentoo Linux	Custom Gentoo Linux
Computer Hardware	Intel XEON processor – closed system	AMD based processor – closed system	AMD based processor – closed system
Internet Communications	Wireless 802.11 b/g/n	Wireless 802.11 b/g/n	Wireless 802.11 b/ g/n
Scanning Wand Computer Interface	USB 3.0 Interface	Proprietary serial interface to custom PCI adapter	Proprietary serial interface to custom PCI adapter
Scanning Wand Imaging Sensor(s)	Single	Three	Three
Scanning Wand LEDs (# and wavelength)	6 LEDs (465 nm wavelength)	192 LEDs (465 nm wavelength)	192 LEDs (465 nm wavelength)
Isolation Transformer	Powertronix Isolation Station™	Custom built	Custom built

Accuracy Comparison		
Parameter	**3M True Definition Scanner (K122467)**	**Lava COS (K073199 and K081961)**
Initial Average Error (%)	0.13%	0.57%
Initial Max Error (%)	0.22%	0.74%

Accessories Comparison				
Item	**3M True Definition Scanner (K122467)**	**3M ESPE Lava C.O.S. (510(k)# K073199)**	**3M Unitek Lava C.O.S. (510(k) #081961)**	**Comments**
Contrast patterning Powder	Composition: • titanium dioxide • amorphous silica • aluminium hydroxide • synthetic amorphous silica	Composition: • titanium dioxide • amorphous silica • aluminium hydroxide • synthetic amorphous silica	Composition: • titanium dioxide • amorphous silica • aluminium hydroxide • synthetic amorphous silica	No change- the same powder described in K073199 was used in K081961 and will be used for the 3M True Definition Scanner
Powder delivery device	Battery (9V) powered sprayer	Battery (9V) powered sprayer	Battery (9V) powered sprayer	No change – the same sprayer described in K073199 was used in K081961 and will be used for the 3M True Definition Scanner

3M ESPE concludes that 3M True Definition Scanner is substantially equivalent to the named predicate devices (3M ESPE Lava C.O.S. (K073199) and 3M Unitek Lava C.O.S (K081961)). Any differences between the 3M True Definition Scanner and the predicate(s) do not raise new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 20, 2012

3M Company
C/O Mr. Mark Job
Regulatory Technology Services, Limited Liability Company
1394 25TH Street, North West
Buffalo, Minnesota 55313

Re: K122467
Trade/Device Name: 3M True Definition Scanner (Model G5)
Regulation Number: 21 CFR 872.3661
Regulation Name: Optical Impression Systems for CAD/CAM
Regulatory Class: II
Product Code: NOF
Dated: November 2, 2012
Received: November 5, 2012

Dear Mr. Job:

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,

Kwame O. Ulmer

Digitally signed by Kwame O. Ulmer
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Kwame O. Ulmer, 0.9.2342.19200300.100.1.1=13001183618
Date: 2012.11.20 14:32:07 -05'00'

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

Indications for Use

510(k) Number (if known): K122467

Device Name: 3M True Definition Scanner (Model G5)

Indications for Use:

3M True Definition Scanner is an optical impression system used to record the topographical characteristics of the dentition and/or full arch and preparation areas (including features such as implant scan locator fixtures, braces, brackets, etc.). In addition it can record the topographical characteristics of the oral anatomy (such as soft tissue, gingivae and palate).

The three dimensional (3D) model generated from the scan may be further used for the design and manufacturing of dental restorations including implant supported prostheses and partial frameworks, and can be used to design and manufacture physical models of the teeth.

It may also be used in conjunction with production of orthodontic appliances, retainers and accessories.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2012.11.20 12:13:34 -05'00'

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

510(k) Number: K122467