Reference 510(K) Number: K103586

MAR 3 0 2011

510(k) Summary

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

A. SUBMITTER INFORMATION

Company Name:	IOS Technologies, Inc.
Company Address:	3978 Sorrento Valley Blvd. Suite 200 San Diego, CA 92121
Company Phone:	(858) 202-3363
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Contact Person:	Duane M. Durbin (858) 202-3363
Date Summary Prepared:	January 26, 2011

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	IOS FastScan Spray
21 CFR Reference:	872.3660
21 CFR Common Name:	Impression Material
Classification:	Class II
Panel:	Dental ELW

C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name: CEREC Opti Spray, K080882 (4/11/2008)

D. DEVICE DESCRIPTION

The IOS FastScan Spray is a coating medium applied by a dentist, by spraying onto the area of interest on the teeth and gums. After the coating application, the IOS FastScan System is used to optically capture a 3D impression of the coated dentition. Once the dentist has completed the optical impression, the patient's mouth is rinsed and suctioned to remove the IOS FastScan Spray. The IOS FastScan Spray consists of a pigment suspension in ethanol with a fluorinated hydrocarbon propellant.

E. INDICATIONS FOR USE

The IOS FastScan Spray is indicated as a coating medium for optical impressions with the IOS FastScan System. It aids in intraoral topographical recordings of prepared and unprepared teeth and their surroundings.

F. TECHNOLOGICAL CHARACTERISTICS:

The IOS FastScan Spray consists of a pigment suspension in ethanol with a fluorinated hydrocarbon propellant. The contents are mixed together and packaged in 50mL spray cans. Disposable extension tubes and nozzles are used to apply the spray to the dentition.

G. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Characteristic	IOS FastScan Spray	Predicate CEREC Opti Spray
Principles of Operation	Spray can with a fluorinated hydrocarbon propellant used to expel a pigment suspension comprised principally of titanium oxide and ethanol through a nozzle	Spray can with a fluorinated hydrocarbon propellant used to expel a pigment suspension comprised principally of titanium oxide and ethanol through a nozzle
Predicate Device	CEREC Opti Spray	Unknown
Volume of Spray Can	50mL	50mL
Extension Tube Length	85mm	85mm
Nozzle design	Rotates to allow direct aim of spray at dentition	Rotates to allow direct aim of spray at dentition
Patient Contamination Control	Discard extension tube and nozzle after each use	Discard extension tube and nozzle after each use
Shelf Life	36 months	36 months
Indication for Use	The IOS FastScan Spray is indicated as a coating medium for optical impressions with the IOS FastScan System. It aids in intraoral topographical recordings of prepared and unprepared teeth and their surroundings.	CEREC Opti Spray is indicated as a coating medium for optical impressions with the CEREC system. It aids in intraoral topographical recordings of prepared and unprepared teeth and their surrounding.

H. SUMMARY OF NON-CLINICAL TESTING DATA

Non-clinical studies were performed to assess the performance characteristics of the IOS FastScan Spray in comparison to the performance characteristics of the predicate device CEREC Opti Spray. The studies involved the repeated applications of the FastScan spray or the predicate CEREC Opti Spray to a master typodont model which was then digitally scanned to capture an optical impression of the typodont model. Comparison of the optical impressions captured with the IOS FastScan Spray showed no statistically significant difference in the accuracy of the 3D digital models derived from the impressions captured with the IOS FastScan Spray versus the impressions captured using the predicate CEREC Opti Spray.

To evaluate the biocompatibility of the IOS FastScan Spray materials, cytotoxicity testing as per EN ISO 10993-5, and irritation and sensitivity testing per EN ISO 10993-10 was performed. The testing found that "no cytotoxic, irritative and sensitizing effects should be expected".

To assess Acute Systemic Toxicity, an Acute Oral Toxicity study was also performed. The study found that there were no signs of toxicity or mortality from an acute oral dose of the IOS FastScan Spray.

I. SUMMARY OF CLINICAL TESTING DATA

Clinical studies were performed, involving 20 dentists with clinical testing taking place at the dental practice of each of the participating dentists. The study involved testing the performance of the IOS FastScan Spray in comparison to the CEREC Opti Spray by having each dentist take an *in-vitro* digital optical impression of the same master typodont dental model test specimen and an *in-vivo* digital optical impression of the same section of dentition of a volunteer subject. The digital optical impression data for each dentist and each spray were saved and compared for validation of precision and to compare the performance of the IOS FastScan Spray device against the performance of the predicate CEREC Opti Spray device.

The same volunteer subject, a 59 year old male, was involved with the clinical in-vivo testing at all 20 sites.

The clinical *in-vitro* and *in-vivo* impression 3D model accuracy data show that the 20 dentists involved in the study achieved essentially the same accuracy result with the IOS FastScan Spray as was achieved with the CEREC Opti Spray.

There were no adverse events or complications experienced during the clinical testing.

J. CONCLUSION, SUBSTANTIAL EQUIVALENCE

The IOS FastScan Spray is substantially equivalent to the CEREC Opti Spray. These devices are both comprised of a spray can with a fluorinated hydrocarbon propellant used to expel a pigment suspension comprised principally of titanium oxide and ethanol through a nozzle. Both devices are indicated as a coating medium for optical impressions to aid in intraoral topographical recordings of prepared and unprepared teeth and their surrounding.

The IOS FastScan Spray performance was assessed in non-clinical and clinical studies and found to have a performance substantially equivalent to that of the predicate device, the CEREC Opti Spray.

Biocompatibility and toxicity studies conducted with the IOS FastScan Spray have found that no cytotoxic, irritative, sensitization, or acute systemic toxicity effects should be expected and it is concluded that the safety of the IOS FastScan Spray device for the intended use is substantially equivalent to the predicate device.

IOS Technologies is claiming substantial equivalence of the IOS FastScan Spray to other currently marketed coating mediums for optical impressions, specifically, the CEREC Opti Spray which was cleared under K080882 in April, 2008.

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

Mr. Duane Durbin
President
IOS Technologies, Incorporated
3978 Sorrento Valley Boulevard, Suite 200
San Diego, California 92121

MAR 30 2011

Re: K103586
Trade/Device Name: IOS FastScan Spray
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: February 14, 2011
Received: February 17, 2011

Dear Mr. Durbin:

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,

for

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

Enclosure

Indications for Use Form (Text Version)

Indications for Use

510(k) Number (if known): K103586

Device Name: IOS FastScan Spray

Indications for Use:

The IOS FastScan Spray is indicated as a coating medium for optical impressions with the IOS FastScan System. It aids in intraoral topographical recordings of prepared and unprepared teeth and their surroundings.

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K103586