SECTION 5: 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: July 26, 2013

510(k) number: K131101

Applicant Information:
Cadent, Ltd.
An Align Technology Company
2560 Orchard Parkway
San Jose, CA 95131

AUG 2 6 2013

Contact Person
Manas M Lele
Regulatory Affairs Analyst
Align Technology, Inc.
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Device Information:

Trade Name:	iTero Software
Classification:	21 CFR 872.3630
Classification Name:	Abutment, Implant, Dental, Endosseous

Description:

The iTero software is used with the iTero scanner in capturing 3D digital impressions of teeth, oral soft tissue and structures, and bite relationship. The software supports dental professionals in acquiring very accurate digital images which can be edited and used for planning and simulation. The software controls the export of the data by a secured internet connection for CAD/CAM fabrication of dental restorations, orthodontic devices, abutments, and accessories.

Intended Use:

iTero software is used with the iTero scanner in capturing 3D digital impressions of teeth, oral soft tissue and structures, and bite relationship. iTero software controls the processing of the data, facilitating the integration of data, and exporting of the data for CAD/CAM fabrication of dental restorations, orthodontic devices, abutments, and accessories. In addition to scan data, various patient and case information can be imported/exported or used for simulation purposes. Other functions are available for verification and service of the system and to serve as an order management tool.

Equivalent Device:

iTero Software is substantially equivalent in intended use and/or method of operation to the following devices:

Name	Manufacturer	510(k) #
3M Lava Software	Brontes Technologies, Inc./3M	K062493
Straumann Visual Software	Institut Straumann, AG	K093113

Summary of Technical Characteristics:

Characteristic	Cadent iTero Software	3M Lava Software	Straumann Software
Intended use statement	iTero software is used with the iTero scanner in capturing 3D digital impressions of teeth, oral soft tissue and structures, and bite relationship. The software controls the processing of the data, facilitating the integration of data, and exporting of the data for CAD/CAM fabrication of dental restorations, orthodontic devices, abutments, and accessories. In addition to scan data, various patient and case information can be imported/exported or used for simulation purposes. Other functions are available for verification and service of the system and to serve as an order management tool.	The Lava software is used with the Lava scanner, an all-ceramic system for the CAD/CAM fabrication of dental restorations, abutments, orthodontic devices, and accessories. The software controls the measuring process, processing of the measurement data (3D-CAD tool), and export of the data to the milling machine. In addition, various patient and case information elements can be entered. Other functions are available for verification and service of the measuring system. The Lava software also facilitates the transfer of 3D data from a scanner to a remote milling machine via internet.	Straumann etkon_visual is a software device intended to import patient-specific data from a scanner for CAD (computer aided design) design of individual dental restorations like crowns, bridges, inlays, onlays, veneers, and abutments. The visual software also facilitates the transfer of 3D data from a dental lab to a remote milling center by internet connection and serves as an order management tool.
Operating System	Windows	Linux	Windows
Programming Language	C++ and C#	C++	C++ and Java
Import/Export Data Format	STL	STL	STL
Data Visualization	2D and 3D	2D and 3D	3D

Characteristic	Cadent iTero Software	3M Lava Software	Straumann Software
Principles of Operation:			
• Entering and Reviewing Patient Data	• Yes	• Yes	• Yes
• Scanning	• Yes	• Yes	• Yes
• Data Review and Editing	• Yes	• Yes	• Yes
• Data Transfer	• Yes	• Yes	• Yes
• System Operation and Process Management	• Yes	• Yes	• Yes
• Abutment Design and Manufacturing	• No	• No	• Yes

Test Results:

Results of verification/validation testing demonstrate that iTero Software showed conformity with pre-established specifications and acceptance criteria. The acceptance criteria were established in order to demonstrate that iTero Software is safe and effective for its intended use.

Conclusion:

Based on the intended use, product, performance, and software information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices identified.

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

August 26, 2013

Cadent, Limited An Align Technology Company
C/O Mr. Manas M. Lele
Regulatory Affairs Analyst
2560 Orchard Parkway
San Jose, California 95131

Re: K131101
Trade/Device Name: iTero Software
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA, NOF
Dated: July 26, 2013
Received: July 29, 2013

Dear Mr. Lele:

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 contact 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. 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 Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K131101

Device Name: iTero Software

Indications for Use:

iTero software is used with the iTero scanner in capturing 3D digital impressions of teeth, oral soft tissue and structures, and bite relationship. iTero software controls the processing of the data, facilitating the integration of data, and exporting of the data for CAD/CAM fabrication of dental restorations, orthodontic devices, abutments, and accessories. In addition to scan data, various patient and case information can be imported/exported or used for simulation purposes. Other functions are available for verification and service of the system and to serve as an order management tool.

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)

Sheena A. Green -S
2013.08.26 11:31:23 -04'00'

for M. Susan Runner, DDS, MA

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
510(k) Number: K131101