DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Trident s.r.l.
% Mr. Claude Berthoin
President
Denterprise International, Inc.
100 East Granada Blvd., Suite 219
ORMOND BEACH FL 32176

March 10, 2016

Re: K160386
Trade/Device Name: ReadeR, ViewER, QuickScan PSP
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: February 08, 2016
Received: February 11, 2016

Dear Mr. Berthoin:

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160386

Device Name
ReadeR, VieweR, QuickScan PSP

Indications for Use *(Describe)*

ReadeR is a dental imaging system indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510k FDA Consulting

Medical Device Clearance

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510(k) Summary

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Date Prepared: February 08, 2016

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Device Classification

Trade/Model Names:	ReadeR, VieweR, QuickScan PSP
Common Name:	Computed Radiography Scanner System
Classification Name:	System, X-Ray, Extraoral Source, Digital
Regulation Name:	Extraoral source x-ray system
Regulation Number:	21 CFR 872.1800
Product Code:	MUH
Regulatory Class:	2
510k Review Panel:	Radiology
Regulation Medical Specialty:	Dental

Predicate Device

The subject device claims equivalence to the following legally marketed predicate:

510(k) Number:	K143703
Date Cleared	March 18, 2015
Trade Name:	NICAL SMART MICRO CR System for Intraoral Dental Images
Common Name:	Computed Radiography Scanner System
Classification Name:	System, X-ray, Extraoral Source, Digital
Regulation Name:	Extraoral source x-ray system
Regulation Number:	21 CFR 872.1800
Product Code:	MUH
Regulatory Class:	2
Medical Specialty:	Dental
510k Review Panel:	Radiology

Indications for Use

ReadeR is a dental imaging system indicated for capturing, digitization and processing of intraoral x-ray images stored in imaging plate recording media.

Intended Use

ReadeR system is intended to be used only by dentist and other qualified dental professionals to process x-ray images exposed to the imaging plates from the intraoral complex of the skull.

It is possible for both tooth decay and periodontal disease to be missed during a clinical exam, and radiographic evaluation of the dental and periodontal tissues is a critical segment of the comprehensive oral examination. In some cases extensive decay has been overlooked by a number of dentists prior to radiographic evaluation. So, the sensors and the PSP plates are in the best interest of the patient for improved healthcare. The ReadeR is a necessity for the dental office that is using the PSP plates.

Device Description

The ReadeR is a computer radiography system which produces the x-ray diagnostic image in digital format instead of using traditional screens and film. This device does not have a wireless transmission. The device utilizes reusable x-ray storage phosphor plate (IP) that is sensitive to x-ray and stores latent image when it is exposed to x-ray. After x-ray exposure to the x-ray storage phosphor plate, x-ray storage phosphor plate is scanned by means of laser in the device. Latent image in the x-ray storage phosphor plates is released in a form of light by laser scanning. Then the light is collected and converted into a form of digital image. The signal processing is made to the digital image data such as the digital filtering, the gain and offset correction and flat fielding. The image can then be viewed on a computer workstation, adjusted if necessary, the stored locally, sent to an archive, printed or sent to PACS system.

After acquisition of the latent image from the x-ray storage phosphor plate, it is erased thoroughly to be reused.

Comparison of Technological Characteristics with Predicate

The indications for use of the subject and predicate devices are identical and the technologies are substantially equivalent.

The imaging plates are exposed to x-rays while in the patient's mouth. The plates are removed and scanned by the scanning device. The images can be viewed by the dentist and stored on a personal computer. The plates are then erased and reused.

Patient cross contamination is prevented by the use of disposable, single use plate covers.

The imaging plates are identical to those used in the predicate device, as both systems are sharing the main part (CR Reader), the only difference with the subject and predicate device is the outside cover of the devices for private labeling. (The predicate device is horizontal and the subject device is vertical.)

The following table compares technological and other characteristics of the subject and predicate device.

Table of Comparison

		Trident ReadeR 510(k) number unknown	**Nical Smart Microchip CR K 143703**
Intended Use		The ReadeR system is indicated for capturing, digitization and processing of intra oral X-Ray images stored in imaging plate recording media.	Nical Smart Microchip CR system is indicated for capturing, digitization and processing of intra oral X-Ray images stored in imaging plate recording media.
Physical characteristics	Imaging plate size	Size 0 (22mm x 31mm), Size 1 (24mm x 40mm), Size 2 (31mm x 41mm), Size 3 27mm x 54mm)	Size 0 : 22 x 31mm Size 1 : 24 x 40mm Size 2 : 31 x 41mm Size 3 : 27 x 54mm

		Trident ReadeR 510(k) number unknown	Nical Smart Microchip CR K 143703
	Effective pixel pitch	30 μ	30 μ
	Spatial resolution	10.5 lp/mm @ 30um	10.5 lp/mm @ 30um
	Image Matrix	Size 0: 343 x 484 @ 64um 628 x 885 @ 35um	Size 0: 343 x 484 @ 64um 628 x 885 @ 35um
		Size 1: 375 x 625 @ 64um 685 x 1143 @ 35um	Size 1: 375 x 625 @ 64um 685 x 1143 @ 35um
		Size 2: 484 x 640 @ 64um 886 x 1171 @ 35um	Size 2: 484 x 640 @ 64um 886 x 1171 @ 35um
		Size 3: 891 x 1783 @ 30 um	Size 3: 891x 1783 pixel 30 um
	Weight	4.6 kg	4.7 kg
	Imaging device	High Sensitivity Photo Multiplier Tube (s-PMT)	High Sensitivity Photo Multiplier Tube (s-PMT)

Operational characteristics	Operating Conditions	Temperature :15-30°C Humidity: 15%-95%	RH Temperature: 10 - 40 °C Humidity: 30 - 90% RH
	Power	100 – 240V, 50/60Hz	100 – 240V, 50/60Hz
	Method of imaging	Register Patient -> X-ray Exposure	Register Patient -> X-ray Exposure
	Image receptor	Imaging plate	Imaging plate

Functional characteristics	Output data	DICOM 3 compatible	DICOM 3 compatible
	Performance	MTF: 65Kv 0,1 sec exposure. 100%. 1 lp/mm 95%. 3 lp/mm 80%. 5 lp/mm 30%. 10 lp/mm	MTF: 70 kV 0.08 sec exposure. 55% 1 lp/mm 11% 3 lp/mm
	Defect compensation	By Imaging plate calibration	By Imaging plate calibration
	Dynamic range	16 bit	16 bit
	Image Processing	Single image processing parameter is used	Single image processing parameter is used
Imaging plate characteristics	Composition	BaSrFBrl:Eu phosphor	BaSrFBrl:Eu phosphor
	Thickness	approx. 350 mm	approx. 350 mm
	Typical luminescence	400 nm	400 nm
	Image Retention	Recommended within 1 hour of exposure.	Recommended within 1 hour of exposure.
Imaging software	Deep-View	Nical Image Plus	
	The two acquisition and imaging software are two Own Brand Labeling (OBL) of the same original software Archimed Suite, that is CE certified with certificate 1575/MDD issued by IMQ (Italy). Deep-View holds the CE certificate number 1749/MDD, while Nical Image Plus holds certificate number 1748/MDD, both release by IMQ (Italy).		
	The two software packages have the same functionalities, and differ only from the aesthetic screens.		

The above comparison shows the subject and predicate devices are substantially equivalent in technology characteristics. The differences are highlighted and none of these differences make the subject device any less safe and effective as the predicate device. The devices vary in weight by 0.1 kg. (ReadeR being lighter in weight) due to the outer covering of the devices. The operating temperatures vary, but these devices are used in an office setting and the temperature will be controlled to a comfortable median temperature of the operating temperature range. This is also due to the outer covering of the two devices being different. The MTF on performance is listed above and the variation is that the subject device is at 0.1 sec dose and the predicate is at 0.08 sec dose, so the percentages are different. All other technological characteristics are identical. The subject and predicate devices are identical except for the outer cover and the subject device stands vertically and the predicate device is horizontal.

Non-Clinical Performance Data

The following performance data is provided in support of the substantial equivalence determination. All tests performed are included in this submission.

Biocompatibility… This device does not require a biocompatibility evaluation. The plate covers are commonly used and have previous approval.

Electrical Safety and EMC… testing was performed by a qualified testing laboratory according to IEC 60601-1 and IEC 60601-1-2. The device met the requirements according to these standards and was performed by Prima Ricercaq & Sviluppo S.r.l. of Italy.

Software … validation of software (EN 62304) and risk analysis (ISO 14971:2012) were performed and were met according to these standards. IEC 62366:2007 for use in conjunction with 60601-1-6:2010 was performed by TUV Rheinland North America and the standards were met.

Performance Testing… Image testing was performed to check image quality and resolution. Some of these test results are shown in the comparison table above. A quality assurance procedure and inspection was performed on the imaging plates and all testing was approved and standards were met since the predicate has CE mark and the same accessories are supplied for the subject device. *Clinical images were provided; these images were not necessary to establish substantial equivalence based on the modification of the device (note CR reader technology that is identical to the predicate) but they provide further evidence in addition to the bench performance data to show that the CR system works as intended.*

Conclusion

The subject and predicate devices have the same intended use and are substantially equivalent in technological characteristics and performance (since they are, in fact, the same device, with different branding for marketing purposes). The ReadeR does not raise any

questions regarding safety and effectiveness since it is the same as the predicate device. The non-clinical data supports and demonstrates the safety of the device.

The conclusion is that ReadeR (ViewеR and QuickScan PSP) warrants a finding of substantial equivalence to the legally marketed original Nical Smart Micro CR System, and therefore, should have clearance for premarket activities in the United States.