



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

NICAL SPA  
% Mr. Daniel Kamm  
Principal Engineer  
Kamm & Associates  
8870 Ravello Court  
NAPLES FL 34114

March 18, 2015

Re: K143703

Trade/Device Name: NICAL SMART MICRO CR System for Intraoral Dental Images  
Regulation Number: 21 CFR 872.1800  
Regulation Name: Extraoral source x-ray system  
Regulatory Class: II  
Product Code: MUH  
Dated: January 28, 2015  
Received: March 6, 2015

Dear Mr. Kamm:

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,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. A faint, semi-transparent "FDA" watermark is visible behind the signature.

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

Enclosure

**Exhibit 4. INDICATIONS FOR USE STATEMENT**

## Indications for Use

510(k) Number (if known)

**K143703**

Device Name

NICAL SMART MICRO CR system for intraoral dental images

Indications for Use (Describe)

NICAL SMART MICRO CR system for intraoral dental images is 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”*

**Exhibit 1. 510(k) SUMMARY**

## 510(k) Summary, K143703

This 510(k) summary information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date prepared: March 2, 2015

1. Company and Correspondent:

NICAL SPA

Via Soffredini, 43 -

20126 Milano Italy

Phone +39 022571110 -

Fax +39 022572207

[www.nical.com](http://www.nical.com)

Prepared by: Roberto Niccolucci, President

2. Device

Trade/Proprietary Name: NICAL/SMART MICRO

Common Name: Computed Radiography Scanner System

Regulation Number: 21 CFR 872.1800

Regulation Name: Extraoral source x-ray system

Regulatory Class: Class II

Product Code: MUH

3. Predicate Device: FireCR Dental, made by 3D Imaging & Simulations Corp., K131442.

4. Indications for Use: The NICAL/SMART MICRO Dental Imaging System is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.

5. Description: The NICAL/SMART MICRO is a Computed Radiography System which produces the X-ray diagnostic image in digital format instead of using traditional screens and film. This 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 plate is released in a form of light by laser scanning. Then the light is collect 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 & offset correction and flat fielding. The image can then be viewed on a computer workstation, adjusted if necessary, then 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. Details: A laser diode is focused on the plate with a diameter of 30  $\mu\text{m}$ , total power is 35 mW (CW) at wavelength from 620 to 650  $\mu\text{m}$ . The blue light (400 nm) is collected from a light guide (NICAL patent) and sent to a Hamamatsu photomultiplier (PMT). Wavelength (Peak): 420 nm. The signal output from PMT is digitized from a 16 bit A/D converter. The 16 bit digitized imaging signal is sent to an FTDI 2232HL IC that contains all the logic to interface to USB2 standard. The time to read a full image depends on the size of the plate: size 0: 5 seconds; size 3: 9 seconds.

6. Comparison with predicate device: The indications for use and the technologies employed are virtually identical to those of the predicate. Imaging plates are exposed to x-rays while in the patient's mouth. The plates are removed and scanned by the scanning device. The resulting images can be viewed by the dentist and stored on a personal computer. The plates are then

erased and can be reused. Patient cross contamination is prevented by the use of single use barrier envelopes placed over the plates. The imaging plates are identical to those used in the predicate device. Comparison of the test results: The MTF performance (see chart below) is superior on the Nical system as compared to the predicate. The effective pixel pitch is smaller, 30 um vs 35 um giving slightly better overall resolution. This shows up in a comparison of the spatial resolution: 9.0lp/mm @ 35um on the predicate vs. 10.5 lp/mm @ 30um on the Nical device. A detailed comparison table follows.

|                   |                       |   |   |
|-------------------|-----------------------|---|---|
|                   |                       | FireCR Dental<br>3D Imaging & Simulations<br>Corp.  | NICAL/SMART MICRO Dental Imaging<br>System  |
|                   | 510(k) number         | K131442   | K143703   |
|                   | Intended Use          | The FireCR Dental imaging system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.  | The NICAL/SMART MICRO Dental Imaging System is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.     |
| Physical<br>Char. | Overall Dimensions    | Reader<br>185 x 100 x 293mm   | Reader<br>110x154x270 mm  |
|                   | Imaging Area          | Size 0 : 22 x 31mm<br>Size 1 : 24 x 40mm<br>Size 2 : 31 x 41mm<br>Size 3 : 27 x 54mm<br>Size 4c : 48 x 54mm   | Size 0 (22mm x 31mm),<br>Size 1 (24mm x 40mm),<br>Size 2 (31mm x 41mm),<br>Size 3 (27mm x 54mm)<br>N/A  |
|                   | Effective Pixel Pitch | 35um, 64um  | 30 um.  |
|                   | Spatial Resolution    | 9.0lp/mm @ 35um   | 10.5 lp/mm @ 30um   |
|                   | Image Matrix          | Size 0<br>343 x 484 @ 64um<br>628 x 885 @ 35um<br>Size 1<br>375 x 625 @ 64um<br>685 x 1143 @ 35um<br>Size 2<br>484 x 640 @ 64um<br>886 x 1171 @ 35um<br>Size 3<br>421 x 843 @ 64um<br>771 x 1542 @ 35um<br>Size 4c<br>750 x 843 @ 64um<br>1370 x 843 @ 35um | Size 0<br>726x1024 pixel 30 um.<br><br>Size 1<br>792x1321 pixel 30 um.<br><br>Size 2<br>1024x1354 pixel 30 um.<br><br>Size 3<br>891x1783 pixel 30 um.<br><br>Not applicable |

|                  |                     | FireCR Dental<br>3D Imaging & Simulations<br>Corp.                                | NICAL/SMART MICRO Dental Imaging<br>System  |
|------------------|---------------------|---|---|
|                  | Photo               |  |         |
|                  | Weight              | 4.7kg   | 4.6kg   |
|                  | Imaging Device      | High Sensitivity Photo Multiplier Tube (s-PMT)                                    | High Sensitivity Photo Multiplier Tube (s-PMT)  |
| Operational Char | Operating Condition | Temperature :15-30°C<br>Humidity: 15%-95% RH                                      | Temperature: 10 - 40 °C<br>Humidity: 30 - 90% RH  |
|                  | Power               | 100 – 240V, 50/60Hz   | 100 – 240V, 50/60Hz   |
|                  | Methods of Exposure | Register Patient -><br>X-ray Exposure   | Register Patient →<br>X-ray Exposure  |
|                  | X-ray Absorber      | Imaging plate   | Imaging plate   |
| Functional Char. | Output Data         | Dicom3.0 Compatible   | Dicom3.0 Compatible   |
|                  | Performance         | MTF: 70 kV 0.08sec dose.<br>55% 1 lp/mm<br>11% 3 lp/mm                            | MTF: 65Kv 0,1 sec dose.<br>100%. 1 lp/mm<br>95%. 3 lp/mm<br>80%. 5 lp/mm<br>30%. 10 lp/mm |
|                  | Defect Compensation | By Calibration  | By Calibration  |
|                  | Dynamic Range       | 16 bit  | 16 bit  |
|                  | Image Processing    | Single image processing parameter is used   | Single image processing parameter is used   |

|  |                        |  |  |
|--|------------------------|--|--|
|  |                        | FireCR Dental<br>3D Imaging & Simulations<br>Corp. | NICAL/SMART MICRO Dental Imaging<br>System |
|  | DICOM<br>Compatibility | DICOM 3.0 Compliant                                | DICOM 3.0 Compliant                        |

Imaging Plate Comparison

|                              | FireCR Dental<br>3D Imaging & Simulations Corp.   | NICAL/SMART MICRO Dental Imaging<br>System  |
|------------------------------|---|---|
| 510(k) number                | K131442   | K143703   |
| Imaging Plate<br>Composition | BaSrFBrl:Eu phosphor  | BaSrFBrl:Eu phosphor  |
| Plate Sizes                  | Size 0 : 22 x 31mm<br>Size 1 : 24 x 40mm<br>Size 2 : 31 x 41mm<br>Size 3 : 27 x 54mm<br>Size 4c : 48 x 54mm   | Size 0 (22mm x 31mm),<br>Size 1 (24mm x 40mm),<br>Size 2 (31mm x 41mm),<br>Size 3 (27mm x 54mm)<br>N/A  |
| Thickness                    | Thickness: approx. 350 mm   | Thickness: approx. 350 mm   |
| Typical luminescence         | 400 nm  | 400 nm  |
| Image Retention              | Recommended within 1 hour of exposure. Two hours after exposure 70% of the stored energy still is present with no visible loss of information upon readout. Image retention still exceeds 45% after 24h | Recommended within 1 hour of exposure. Two hours after exposure 70% of the stored energy still is present with no visible loss of information upon readout. Image retention still exceeds 45% after 24h |

7. Description of non-clinical testing: Software validation and risk analysis was performed. Electrical safety and EMC testing was performed by a qualified testing laboratory according to IEC 60601-1 and IEC 60601-1-2. A verification report on image testing was performed to check image quality and resolution. A quality assurance procedure has been established for the incoming inspection of the imaging plates. Biocompatibility of the hygienic envelopes has been verified.
8. Description of clinical testing: Clinical Images were reviewed by a Board Certified US based radiologist and were found to be of excellent quality, suitable for the intended use. These images were not necessary to establish substantial equivalence based on the comparison to the predicate device (Note: X-ray storage phosphor plate that is identical to the predicate image plate) but they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended.”
9. Conclusion: Based on the similarity to the predicate device in terms of technology, performance, and indications for use, we conclude that the Nical/Smart Micro Dental Imaging System is substantially equivalent to the predicate device named above.