K132773

DEC 11 2013

510(k) Summary
for
Sirona Dental Systems
SIDEXIS 4

1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstrasse 31
D-64625 Bensheim
Germany
Contact Person: Fritz Kolle
Telephone: +49 6251 16 3294
Date Prepared: August 30, 2013

2. DEVICE NAME

Proprietary Name:	SIDEXIS 4
Common/Usual Name:	Picture archiving and communications system
Classification Name:	System, Image Processing, Radiological

3. PREDICATE DEVICES

- SIDEXIS XG (K013659)
- GALAXIS cleared with (GALILEOS family K0123070)
- Cybermed OnDemand3D (K113543)

4. INTENDED USE

SIDEXIS 4 is software that offers functions for the acquisition, administration, analysis, diagnosis, presentation and transfer of digital or digitized image data, e.g. X-ray images or video recordings, for medical use, predominantly in dentistry.

5. DEVICE DESCRIPTION AND FUNCTION

SIDEXIS 4 combines the two Sirona products GALAXIS and SIDEXIS XG and now integrates 2D and 3D functions. New functions have been implemented (e.g. comparison of two volumes, comparison of two 2D projections).

6. SCIENTIFIC CONCEPT

Not applicable

7. PHYSICAL AND PERFORMANCE CHARACTERISTICS

Not applicable

8. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

SIDEXIS 4 offers similar functions and views as the predicate device Cybermed OnDemand3D (K113543). It offers similar functions to the predicate software parts of SIDEXIS XG and GALAXIS together.

All systems (SIDEXIS XG and GALAXIS are always taken into account together) are typical PACS systems with 3D and 2D image-viewing capabilities for dental imaging devices. They have lots of common options to change the display of the images. With adjustment of brightness, contrast and special filters for SIDEXIS 4, the physician can adjust the display to the preferred style.

9. NON-CLINICAL TESTING

The SIDEXIS 4 system functions have been tested.

Additional tests with technicians and physicians have been performed to compare images from SIDEXIS XG/GALAXIS with SIDEXIS 4.

10. CLINICAL TESTING

Clinical tests have not been performed.

11. CONCLUSION

Based on a comparison of intended use, indications, principle of operation, features and technical data, the SIDEXIS 4 is safe and effective to perform its intended use and is substantially equivalent to the predicate devices.

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

December 11, 2013

Sirona Dental Systems GmbH
% Mr. Fritz Kolle
Fabrikstrasse 31
Bensheim, D-64625
GERMANY

Re: K132773
Trade/Device Name: Sidexis 4
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 19, 2013
Received: September 23, 2013

Dear Mr. Kolle:

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" (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 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

Janine M. Morris
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132773

Device Name
SIDEXIS 4

Indications for Use *(Describe)*
SIDEXIS 4 is software that offers functions for the acquisition, administration, analysis, diagnosis, presentation and transfer of digital or digitized image data, e.g. X-ray images or video recordings, for medical use, predominantly in dentistry.

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)*