DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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QR S.r.l.
% Ms. Simona Daidone
Regulatory Affairs Specialist
Thema S.r.l.
Via Saragat 5
40026- Imola
ITALY

March 31, 2016

Re: K151612
Trade/Device Name: NewTom VGi evo
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: February 03, 2016
Received: February 16, 2016

Dear Ms. Daidone:

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 on last page.

510(k) Number *(if known)*

K151612

Device Name
NewTom VGi evo

Indications for Use *(Describe)*

The NewTom VGi evo is a cone beam computed tomographic x-ray imaging system that acquires sequences of the head including the ENT, dento-maxillofacial complex, temporo-mandibular-joint (TMJ), other areas of human skull and neck with sections of upper cervical spine for use in diagnostic support. The device accomplishes this task by reconstructing a three dimensional matrix of the examined volume and producing two dimensional views (tomographic sections, pan and ceph projections) displaying both two and three dimensional images. The device is operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.

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)*

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510(k) Summary

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

Summary Preparation Date: February 3, 2016

I. GENERAL INFORMATION

Submitter's Name:	QR S.r.l.
Address:	Via Silvestrini 20 37135- Verona Italy
Telephone:	+39 045 8202727
Contact person:	Mr. Lorenzo Bortolotti
E-mail Address:	lorenzo.bortolotti@qrverona.it
Application Correspondent:	Thema S.r.l.
Address:	Via Saragat 5 40026 – Imola Italy
Telephone	+39 0542 643496
Contact person:	Simona Daidone
E-mail Address:	simona.daidone@thema-med.com

II. DEVICE

Trade/Proprietary Name:	NewTom VGi evo
Common Name:	X-ray, tomography, computed, dental
Regulation Name:	Computed Tomography X-ray System

Classification:	(21CFR 892.1750, Class II)
Product Code:	OAS

III. PREDICATE DEVICE

Primary Manufacturer:	QR S.r.l
Device Name:	NewTom VGi
Regulation Name :	Computed Tomography X-ray System
Classification No :	21CFR 892.1750, Class II
Product Code:	OAS
510(k) Number:	K130442

IV. DEVICE DESCRIPTION

The medical electrical equipment NewTom VGi evo is an X-ray imaging device comprising an X-ray acquisition system and the control box, for producing two and three dimensional views for computation and display. It is manufactured by QR s.r.l. and the applicable product code is OAS, Regulation 21CFR 892.1750 Computed tomography x-ray system, Class II.

NewTom VGi evo acquires a sequence of X-ray images rotating around the patient's head and then uses these images to reconstruct a three-dimensional matrix of the volume examined and produce two-dimensional views of this volume. These views can be used to reconstruct additional two-dimensional images, on which distances and angles can be measured, and three-dimensional images. Each image produced can then by printed or exported onto optical media.

The NewTom VGi evo hardware system is composed of the scanner unit, the control box and the external workstation, which enables the user to acquire data easily with the aid of the specific software. The software requires Windows 7 64bit operating system.

V. INDICATIONS FOR USE

The NewTom VGi evo is a cone beam computed tomographic x-ray imaging system that acquires sequences of the head including the ENT, dento-maxillofacial complex, temporo-mandibular-joint (TMJ), other areas of human skull and neck with sections of upper cervical spine for use in diagnostic support. The device accomplishes this task by reconstructing a three dimensional matrix of the examined volume and producing two dimensional views (tomographic sections, pan and ceph projections) displaying both two and three dimensional images. The device is operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The NewTom VGi evo x-ray system is substantially equivalent to the following predicate device:

- NewTom VGi, manufactured by QR s.r.l. and cleared in submission K130442

Please note that NewTom VGi (K130442) is the previous version of the proposed device; as far as technical characteristics and components, the proposed device NewTom VGi evo has the same features of the predicate device (K130442).

A comparison of the proposed and the predicate device is presented below.

Intended use comparison

Both the proposed and the parent device are cone beam computed tomography x-ray imaging system that acquires sequences of the head including the ENT, dento-maxillofacial complex, temporo-mandibular-joint (TMJ), other areas of human skull and neck with sections of upper cervical spine for use in diagnostic support. Both the devices accomplish this task by reconstructing a three dimensional matrix of the examined volume and producing two dimensional views (tomographic sections, pan and ceph projections) displaying both two and three dimensional images.

Both the devices are operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.

We would like to point out that the proposed device NewTom VGi evo shares the same intended use of its previous version already cleared (K130442).

Technical and Functional Comparison

Like the predicate device, NewTom VGi evo is a X-ray imaging device, including a X-ray image acquisition system. As the previous version NewTom VGi (K130442), the proposed device acquires a sequence of X-ray images by means of a rotational movement around the patient's head and neck. Starting from such images a three-dimensional matrix representing the examined volume is reconstructed and two-dimensional views of such volume generated. More two-dimensional views, on which distances and angles can be measured, and more three-dimensional views, can be computed and displayed. Each image can be printed and/or stored in a magnetic/optical media.

The main differences between the subject device NewTom VGi evo and the previous version, the predicate device NewTom VGi (K130442), concern the many improvements and benefits for the final user introduced by the subject device:

- The user interface is enhanced, leading to improved usability/reliability.
- The workflow during the positioning of the patient is facilitated, leading to an improved usability of the positioning tool and benefits for both users and patients;
- Scout view adjustment is introduced (scout repositioning from the software)
- Scan modes are enhanced, leading to improved safety and effectiveness due to the possibility of choosing the most appropriate scan parameters
- Interface board between the control board, the power stage and the generator boards.
- Beam limiter with larger aperture
- Different fastening structure for the monoblock and the flat panel detector.
- X-ray control board and relative firmware.
- New NNT software version for new image chain management.
- Operator console with display.
- C-box restyling with board rack arrangement.
- Covers for better ergonomics (patient size) and better aesthetics.

- ***Energy used and delivered***

The proposed device has the same nominal input voltage, frequency and line as the parent NewTom VGi (K130442). Its max working current is higher and uses an x-ray tube with higher anodic current.

- ***X-ray generator***

The proposed device uses a different X-ray generator than the parent NewTom VGi (K130442) but both generators are manufactured by IAE spa.

- ***Flat Panel Detectors:***

NewTom VGi evo is equipped with a larger Amorphous Silicon flat panel X-ray detector than the predicate device: a larger flat panel allows to have a bigger field of view to detect larger areas than the predicate device NewTom VGi (K130442).

- ***X-ray Emission and exposure time***

The exposure time emission is lower than the parent NewTom VGi (K130442), so lower exposure time emissions translate in increased safety and health for the users and the patients subjected to the NewTom VGi evo.

- ***Software***

As per the predicate devices, the software requires a Microsoft Windows OS. NewTom VGi evo is supplied with the same proprietary software (NNT) of the predicate device NewTom VGi (K130442) but the proposed device provides an updated version of the software. It performs the same functions and algorithms (Filtered Back Projection) of the previous versions but there are many improvements in the graphic and user interface. Moreover, the new software version introduces the possibility to elaborate the three-dimensional images acquired during the scan in order to reconstruct them in a complete set of highly-detailed 2D images.

There are no differences in the device's firmware and in the control operator panel. The systems provide the same electronic hardware and have the same architecture interaction of the parent devices.

VII. PERFORMANCE DATA

The fundamental technological characteristics of the subject device NewTom VGi evo and predicate device NewTom VGi (K130442) are similar, so there are no significant difference in efficiency and safety. Electrical safety, EMC/EMI testing, biocompatibility consideration, performance and image quality testing, verification and validation testing were performed to support the hardware and software modifications. The subject device was designed, tested and found to be compliant with standards IEC 60601-1 (Ed. 3, 2005), IEC 60601-1-2 (Ed. 3, 2007), IEC 60601-1-3 (Ed. 2, 2008), IEC 60601-1-6 (Ed, 3, 2010), IEC 62366 (Ed. 1, 2015), IEC 60601-2-63 (Ed. 1, 2012), IEC 60825-1 (Ed. 2, 2007) and IEC 62304 (Ed. 1, 2006).

A risk analysis was performed to analyze the hazards associated with the changes. Non clinical considerations according to FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" were performed.

The clinical considerations on the images in terms of quality and effectiveness sustained the diagnostic reliability and usefulness of images produced by the NewTom VGi evo applications.

In addition to the 2-D performance data recommended by the Solid State X-ray Imaging guidance, 3-D lab performance data (including 3-D MTF and NPS) was provided to evaluate the cone-beam CT mode of operation.

VIII. CONCLUSIONS

As shown above, there are slight differences between the proposed and the predicate devices. All of these changes aim to improve the experience, safety and quality of the users of the NewTom VGi evo.

The principal components and the technical features of the proposed device NewTom VGi evo are identical or equivalent to the parent NewTom VGi (K130442), already cleared.

The design, the functions and technical characteristics of the proposed NewTom VGi evo are substantial equivalent to the predicate devices.

The level of safeness of the proposed NewTom VGi evo, with its new characteristics, is equivalent to the predicate device.

For these reasons we believe that the proposed NewTom VGi evo can assure more effective acquisitions of the head including the ENT, dento-maxillofacial complex, temporo-mandibular-joint (TMJ), other areas of human skull and neck with sections of upper cervical.

Due to all the above described reasons, we can conclude that NewTom VGi evo is substantially equivalent to NewTom VGi and can be considered safer and more effective than the predicate device for the intended use presented.