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

July 3, 2013

QR s.r.l.
% Mr. Claude Berthoin
President
Thelma USA
110 E. Granada Blvd., Suite 209
ORMOND BEACH FL 32176

Re: K130442
Trade/Device Name: NewTom VGi and NewTom 5G
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: June 5, 2013
Received: June 7, 2013

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.

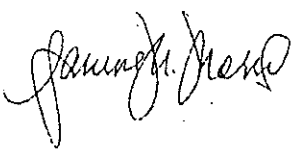
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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,



Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130442

Device Name: NewTom VGi

Indications for Use:

NewTom VGi is a cone beam computed tomography x-ray imaging system that acquires a 360 degree rotational 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 of this volume, displaying both two and three dimensional images. The device is operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K130442

Indications for Use

510(k) Number (if known): K130442

Device Name: NewTom 5G

Indications for Use:

NewTom 5G is a cone beam computed tomography x-ray imaging system that acquires a 360 degree rotational 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 of this volume, displaying both two and three dimensional images. The device is operated and used by physicians, dentists, x-ray technologists and other legally qualified professionals.

NewTom 5G is especially designed for:

- dento-maxillo-facial complex imaging;
- teeth, mandible and jaw imaging for implant planning;
- temporal-mandibular joint (TMJ) imaging;
- ear, nose and throat (ENT) analysis;
- sections of upper cervical-spine imaging;

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Division of Radiological Health
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