JUL 3 1 2001



12 SUMMARY OF SAFETY AND EFFECTIVENESS:
Submission in accordance with the requirements of 21 CFR Part 807.87(h)

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|---|---|
| 1) Submitter | : MEDIS m*edical imaging systems* B.V. |
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| Contact Person | : J.I. Hollander, Quality Coordinator |
| Prepared | : May 21, 2001 |

| | |
|---|---|
| 2) Device Name | : QCU-CMS analytical software package |
| Common Name | : QCU-CMS |
| Device Class. Name | : System, Image Processing |
| Regulation Number | : 21 CFR 892.1560 (90 LLZ; Class II) |

3) Predicate Device : TomTec: 510(k) K993394

4) Description of the device:
QCU-CMS is a state-of-the-art analytical software tool designed for Windows NT operating systems. QCU-CMS analytical software facilitates the import and visualization of ultrasound images via CD-ROM and digital network. The QCU-CMS functionality is independent of the ultrasound equipment vendor. QCU-CMS, using automated contour detection, provides quantitative analysis with objective and reproducible data of length and diameter, area and volume in regions of interest. The results of selected analysis can be reported in user-defined configuration, exported in general formats and transported for storage via communication with standard Microsoft office packages.

5) Intended use:
QCU has been developed for the objective and reproducible analysis of intravascular ultrasound images. Intended purposes are:
1. Supporting clinical diagnoses about stenosis and/or control of the placement of intervention devices;
2. Supporting subsequent clinical decision making purposes;
3. Supporting the use in clinical research trials, directed at studying changes in vessel conditions over time as a result of interventions and or medication.

6) Substantial equivalence Information:
The QCU-CMS software is substantially equivalent to the predicate devices of TomTec K993394 "Echo-Scan 4.x and Easy-Scan 1.x" by using the same technological characteristics and intended use.

CONCLUSIONS RESPECTING SAFETY and EFFECTIVINESS:

It is the opinion of MEDIS *medical imaging systems* B.V. that QCU-CMS is safe and potential hazards are controlled by a risk management plan for the software development process (see Appendix C), including hazard analysis (see Appendix D), verification and validation tests (see Appendix E). Evaluation by hospitals and literature (see Appendix F) support this statement.
In MEDIS' opinion the level of concern for the stand-alone software to view images is 'minor' and that the use of QCU analytical software does not change the intended use of ultrasound scanners in practice, nor does the use of software result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 1 2001

Mr. J.I. Hollander
Quality Coordinator
MEDIS Medical Imaging Systems B.V.
Poortgebouw, Rijnsburgerweg 10
2333 AA Leiden
The Netherlands

Re: K011582
QCU-CMS Analytical Software
Dated: May 21, 2001
Received: May 23, 2001
Regulatory Class: II
21 CFR 892.2050/Procode: 90 LLZ
21 CFR 892.1560/Procode: 90 IYO

Dear Mr. Hollander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) NUMBER (IF KNOWN): K011582

DEVICE NAME: QCU Analytical Software Package

INDICATIONS FOR USE:

QCU has been developed for the objective and reproducible analysis of tomograhic images of both lumen and arterial wall of a coronary or vascular segment, in particular the assessment of a stenosis or atherosclerotic plaque. This information supports the possible placement of intervention devices in these vessels. QCU-CMS enables an advanced assessment of vessel, lumen, and stent morphology. It also avoids the very time-consuming conventional manual tracing of boundaries, which suffers from high intra- and inter observer variability. QCU-CMS can be used to control stent placement and to assess in-stent restenosis. QCU software package enables the automatically calculation and the display of various parameters such as: areas and diameters in individual slices; volumes over the segment of interest (Simpson's Rule) for the vessel, lumen and stent contours; plaque and in-stent restenosis parameters.
QCU-CMS analytical software is intended to support all clinicians, i.e. cardiologists, radiologists, and referring physicians involved in the assessment of ultrasound images. When interpreted by a trained physician these parameters may be useful in supporting the determination of a diagnosis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011382