K100092

Section 2 Special 510(k) Summary

Prepared January 7, 2010

FEB 23 2010

2.1 SUBMITTERS NAME

Best NOMOS

2.2 ADDRESS

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2.3 CONTACT

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2.4 DEVICE NAME

Device Trade Name: **CORVUS**
Common/Classification Name: Radiation Therapy Treatment Planning System

2.5 ESTABLISHMENT REGISTRATION NUMBER

Corporate Office Registration Number: 2434141
Manufacturing and Packaging Registration Number: 2434141

2.6 DEVICE CLASS

Class II
Panel: Radiology
Product Code: 90-MUJ
Regulation Number: 21CFR 892.5050

2.7 LEVEL OF CONCERN

Major Level of Concern

We believe the level of concern is Major for CORVUS 09. CORVUS 09 is an accessory to a medical device that has a Major Level of Concern such as delivery systems which use modulated radiation therapy for delivery and planning.

The copy of the complete decision making process for this conclusion is included in Section 13.1.

2.8 STATEMENT OF INDICATIONS FOR USE

The intended use and indications for use for the CORVUS Radiation Therapy Planning System have NOT changed as a result of this modification.

Intended Use

CORVUS is intended for use as a planning tool for conformal radiation therapy. Using operator-supplied input and patient scans, it creates a plan for treatment delivery systems and generates a set of beam weights that, when applied to a compatible system, facilitates delivery of an intensity-modulated 3D conformal radiation therapy treatment. CORVUS is intended only to suggest a delivery plan. It is the physician's responsibility to verify that the dose distributions which would result from plan implementation are appropriate for a particular patient.

The CORVUS system is intended to be used as an integrated system with a modulating device for planning and delivery of conformal radiation therapy. The modulating device can be the NOMOS MIMiC, nomosSTAT MLC, or a supported MLC. CORVUS produces radiation fields which are modulated to conform to the projected tumor volume plus margins. The system tries to achieve target goals while sparing sensitive structures.

Indications for Use

The CORVUS system is a radiation treatment planning package designed to allow medical physicists, dosimetrists, and radiation oncologists to create conformal treatment plans using photon (x-ray) external beam radiation therapy. The treatment plans generated by CORVUS are based upon treatment machine-specific data and are intended to provide a guide to delivering external beam radiation therapy which conforms to the target volume defined by the radiation oncologist.

The CORVUS system is valid for use only with external beam photon therapy; calculations for electrons and intracavity sources (Brachytherapy) are NOT supported.

2.9 DEVICE DESCRIPTION

CORVUS is a semi-automatic planning system: rather than simply verifying a user-designed plan, the system itself suggests a plan. A clinician then reviews and approves the plan.

CORVUS is designed to generate plans for treatment delivery systems that can create multiple radiation patterns composed of pencil beams on which the intensity can be individually controlled. The treatment beams are weighted so that when they are projected into the treatment space they superimpose to give the desired dose distribution.

Each radiation field is generated using one of several optimization methods provided with the system, including simulated annealing and gradient descent.

The treatment beams are set not only to deliver the prescribed dose to the identified target volume, but also to keep the dose to other sensitive volumes below user-defined limits. Planning is done volumetrically: the beam weights for treating the entire target volume are generated simultaneously. The dose matrix is volumetric. The dose to each point is calculated to be that received from all beams and from all gantry angles. Dosage is calculated using a finite size pencil beam (FSPB) algorithm based on the beam characterization of clinically measured data. The degree to which a treatment plan is optimized is determined in part by constraints placed on the planning algorithm. The user has direct control over these constraints, which include dose goals to the target structures, dose limits to the sensitive structures, and the specification of arcs or fixed gantry positions in the treatment plan.

CORVUS treatment plans need not have the isocenter located within the target volume. An unlimited number of targets falling within the treatment volume can be planned for at the same time. Dose may be prescribed for up to 32 structures, 29 of them user-selectable, any number of which may be separate targets or radiation-sensitive structures. Each structure can have a separate dose prescription.

2.10 PREDICATE DEVICE INFORMATION

The CORVUS 09 system is substantially equivalent to the CORVUS 5.0M (K032209). The CORVUS 5.0M was determined to be substantially equivalent to its predicate device as of August 2003..

The fundamental scientific technology for the CORVUS 5.0M and CORVUS 09 systems has not changed. The intended use of the device has not changed. Based upon the performance testing results for CORVUS 09, the system raises no new issues of safety or effectiveness.

2.11 COMPARISON TO THE PREDICATE DEVICE

This section describes the incremental changes from CORVUS 5.0M to CORVUS 09.

Note that for marketing purposes the CORVUS 6.4 version was renamed as CORVUS 08 and CORVUS 7.0 was renamed to CORVUS 09, however internally either may be referred to as its version level.

Hardware and Operating System

CORVUS 5.0M

- Operating System: MacOS X 10.2.6 operating system.
- Workstation: Mac-based Power Pro G4 hardware (based on Apple Power Mac G4 Dual 1.42 Ghz CPU)

- Server: OmnitTech Percheron Intel 860 Dual 2.4 Ghz
- Printer: Xerox Tektronix Phaser 6200 Laser Printer

CORVUS 09

- Operating System: MacOS X 10.5.4 operating system
- Workstation: Intel-based Mac Pro hardware system (based on two 3.2GHz Quad-Core Intel Xeon (8-core)CPUs).
- Physician's Review Workstation: Intel-based iMac hardware system (based on 2.03 Ghz Intel core 2 Duo CPU)
- WACOM Tablet: WACOM CINTIQ 21UX Interactive Pen Display, Graphics Tablet

Note that the development of more powerful computers has eliminated the need for a separate server computer solely for planning, like used in CORVUS 5.0M. The more powerful CORVUS 09 workstation completes the planning locally (on the Workstation) and does not require a Remote Compute Engine (RCE). The Physician's Review Workstation released in CORVUS 09 allows remote plan review through a limited CORVUS application. The printer is no longer included as a component of the device.

CORVUS Software Features

- CORVUS 09 contains the Active Rx feature addition which was introduced in CORVUS version 6.0.
    - ActiveRx is an IMRT optimizer where the user plays an integral role in the optimization process with controls to influence and evaluate the dosimetric tradeoffs before plan delivery. ActiveRx allows CORVUS users to make certain kinds of adjustments to treatment plans in DisplayResults mode by directly manipulating some isodose lines, CDVH curves, delivery efficiency characteristics and dose limit constraints while maintaining physically deliverable plans. ActiveRx displays updated isodose lines, CDVHs, statistics, and treatment plans as the user makes changes. Prior to approval, the system requires the user to submit a plan for final dose calculation.
- CORVUS 09 contains support for formulation and plan output for treatment delivery with the Siemens ONCOR 82 Leaf MLC. This was introduced in CORVUS version 6.0.
- CORVUS 09 contains the feature to use a 2D array (such as MapCheck or MatriXX) to create a Hybrid Plan which is intended to be delivered during the QA process. This involves reorienting beams to gantry vertical in order adapt to the orientation dependence of the 2D array. This was introduced in CORVUS 6.2.
- CORVUS 09 contains support for nomosSTAT (K060859) which was introduced in CORVUS version 6.3.

- CORVUS 09 supports the optional use of WACOM CINTIQ 21UX electronic drawing tablet as an additional interface. This was introduced in CORVUS 08.
- CORVUS 09 introduces improved dose calculation (Lateral Disequilibrium Inclusive (LDI) heterogeneity correction algorithm) applicable for all iterations of the optimization thereby improving treatment plans in low-density regions such as the lungs. This option was not available in any prior software version.
- CORVUS 09 introduces improved leakage calculation for Varian and Siemens Multi-Leaf Collimators (MLCs). Prior versions of CORVUS incorporated this type of leakage calculation for Elekta MLCs.

While considering these differences it is important to note that CORVUS 09 prepares equivalent treatment plans outside of low density regions as produced by CORVUS 5.0M. The process through which CORVUS accepts image and user input, optimizes plans through applying simulated annealing or gradient descent to cost functions, formats and displays results, and performs all other treatment planning steps have not changed. The algorithms and methods used by CORVUS 5.0M are equivalent to CORVUS 09 except for the inclusion of the improved Lateral Disequilibrium Inclusive (LDI) heterogeneity correction algorithm. This has improved dose calculation in low-density regions. CORVUS 09 also improves the leakage calculation in Multi-Leaf Collimators (MLCs). The process flow and user interface remain the same for CORVUS except for the inclusion of a user optional post optimization interactive tool (Active Rx).

The incremental changes since the latest CORVUS 510(k) were reviewed. We believe that this Special 510k submission is warranted for inclusion of the new Lateral Disequilibrium Inclusive (LDI) dose calculation in CORVUS 09.

Other incremental changes are reviewed. NO particular change NOR the sum of the incremental changes between CORVUS 5.0M and CORVUS 08 could significantly affect the safety or effectiveness of the device.

- Active Rx did not change the performance specifications in a manner that could affect the safety and effectiveness of the device. The final dose calculation upon which clinical users approve the plan was not substantially modified. Additionally, the quality assurance techniques that are used clinically such as phantom delivery still apply.
- The Siemens ONCOR 82 Leaf MLC support did not affect the safety and effectiveness of the device. This support is similar to prior supported MLCs with analogous design control. Additionally, the quality assurance techniques that are used clinically such as phantom delivery still apply.
- Support of a 2D array (such as MapCheck® or MatriXX™) to create a Hybrid Plan is substantially similar to existing QA plan functionality.
- The support of nomosSTAT (K060859) is substantially equivalent to the support of the MIMiC(K940412) and Autocrane(K013036) systems by CORVUS 5.0M.

- The support of the WACOM CINTIQ 21UX electronic drawing tablet did not affect the safety or effectiveness of the device.

Performance Testing Data

A total of 53 comparisons with measurement or comparisons with Monte-Carlo were completed. Equivalence Tests to Confirm Equivalence of the CORVUS software used for validation as compared with the final version are provided in the verification were completed. Anomalies identified in the measured data were investigated and satisfactory resolutions were obtained. The accuracy of the system was confirmed and found to be conformant with our requirements. The plan quality was evaluated and found substantially equivalent. (Refer to Appendix F CORVUS 09 Total Validation Report for further details)

A total of 62 system tests passed the criteria. Module tests were completed for new or modified code. Defect resolutions were verified by an independent evaluator. New or modified code was evaluated by an independent reviewer. Final high level run-through tests were performed to confirm the final functionality of CORVUS. (Refer to Appendix F for the CORVUS 09 Total Verification Summary Report for further details)

CORVUS 09 supports two heterogeneous dose calculation algorithms and introduces improvements to leakage calculation for the Varian and Siemens MLCs:

- The Effective Path Length (EPL) algorithm which has existed in all versions of CORVUS including the predicate version 5.0M and up to version 09. Dosimetric validation of CORVUS' EPL algorithm was performed by comparing it with film measurements, MOSFETS and ion-chambers (See CORVUS 09 Total Validation Report for more details). Treatment plan quality validation was accomplished by comparing treatment plans generated by CORVUS 09 using the EPL algorithm with those generated by a prior version (CORVUS 08) and determined to be substantially equivalent. This was expected as the EPL algorithm has not undergone any substantial changes since CORVUS 5.0M.
- The Lateral Disequilibrium Inclusive (LDI) algorithm which is introduced in CORVUS 09. Dosimetric validation of CORVUS' LDI algorithm was performed similarly by comparing it with film measurements, Mosfets and ion-chambers. Treatment plan quality validation using the new LDI algorithm was done by qualified personnel who are familiar with using an inverse treatment planning system in a clinical setting. (See Appendix F for the CORVUS 09 Total Validation Report for more details)
- Performance testing for the improvements to leakage calculation for the Varian and Siemens MLCs were conducted and found to be conformant with our requirements. (See Appendix F for the CORVUS 09 Total Validation Report for more details)

2.12 SUMMARY OF DESIGN CONTROL ACTIVITIES

The new lateral disequilibrium inclusive pencil-beam algorithm provides improved performance in low density regions such as those found in the lung, while it does not constitute a change of fundamental scientific technology since the planning system creates treatment plans which are confined to conformal radiation therapy using photon radiation as in prior software versions.

The modifications in CORVUS 09 are appropriate for reliance on NOMOS' design control process. The accuracy of the change is evaluated through comparison with medical physics measurements including film measurement, ion chamber measurement, MOSFET measurement, as well as Monte-Carlo calculation using a phantom designed to simulate low-density regions of the patient which are well known to medical physicists skilled in the art of conformal radiation therapy. The quality of the treatment plans is evaluated based upon clinical criteria which are associated with conformal therapy similarly to evaluations which occurred in prior product versions which are well known to medical physicists. Refer to Section 6 for the Declaration of Conformity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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MAR 11 2010

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Re: K100092
Trade/Device Name: CORVUS Radiation Therapy Treatment Planning System
(Model: CORVUS 09)
Regulation Number: 21 CFR 892.5050
Regulation Name: Radiation Therapy Treatment Planning System
Regulatory Class: II
Product Code: MUJ and IYE
Dated: February 23, 2010
Received: February 23, 2010

Dear Mr. Palko:

This letter corrects our substantially equivalent letter of February 23, 2010. 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 (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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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