



Food and Drug Administration
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Best NOMOS
% Vineet Gupta, Ph.D.
Director of R&D
One Best Drive
PITTSBURGH PA 15202

November 25, 2015

Re: K151469

Trade/Device Name: CORVUS Radiation Therapy Planning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: November 9, 2015
Received: November 10, 2015

Dear Dr. Gupta:

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a light grey shadow effect behind the text.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Section 1 Indications for Use Statement

INDICATIONS FOR USE

510(k) Number (if known): K151469

Device Name: CORVUS

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, gamma 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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Traditional 510(k) Summary

A. SUBMITTERS NAME

Best NOMOS

B. ADDRESS

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C. CONTACT

Vineet Gupta, Ph.D.
Phone: (412) 312-6819
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D. DATE PREPARED

Date: 29-May-2015

E. DEVICE NAME

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

F. ESTABLISHMENT REGISTRATION NUMBER

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

G. DEVICE CLASS

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

H. LEVEL OF CONCERN

Major Level of Concern

We believe the level of concern is Major for CORVUS 2011. CORVUS 2011 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.

I. STATEMENT OF INDICATIONS FOR USE

The intended use for the CORVUS Radiation Therapy Planning System has NOT changed as a result of this modification. The indications for use for the CORVUS Radiation Therapy Planning System has been modified to include usage of “gamma rays” (another form of photons) for creating conformal treatment plans. This modification does not change the fundamental principle of using photons for creating conformal treatment plans which is the same as that of its predicate device.

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, gamma 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.

J. 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.

K. PREDICATE DEVICE INFORMATION

The CORVUS 2011 system is substantially equivalent to its primary predicate device CORVUS 09 (K100092). The ViewRay Treatment Planning and Delivery System (K102915) for treatment planning is used only as a reference predicate device. The CORVUS 09 system was determined to be substantially equivalent to its predicate device as of February 2010.

The fundamental scientific technology for the CORVUS 2011 and CORVUS 09 systems has not changed. The intended use of the device has not changed. Based upon the performance testing results for CORVUS 2011 (as detailed in the submission), the system raises no new issues of safety or effectiveness.

L. COMPARISON TO THE PREDICATE DEVICE

This section describes the incremental changes from CORVUS 09 to CORVUS 2011 systems and provides inputs on its equivalence to its predicate devices.

Hardware and Operating System

CORVUS 09 (predicate)

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

CORVUS 2011

Operating System:	MacOS X 10.6.7
Workstation:	Intel-based Mac Pro hardware system (based on two 2.66GHz 6-Core Intel Xeon (12-core) CPUs
WACOM Tablet:	WACOM CINTIQ 21UX Interactive Pen Display, Graphics Tablet

OR

Operating System:	MacOS X 10.6.2
Workstation:	Intel-based Mac Pro hardware system (upgrade of 8-core Mac)
WACOM Tablet:	WACOM CINTIQ 21UX Interactive Pen Display, Graphics Tablet

CORVUS 2011 contains all of the features of CORVUS 09 (K100092) and adds the feature of supporting Cobalt-60 based external beam radiation treatment planning (Gamma Tomotherapy). Similar to Linac based planning, CORVUS 2011 allows users to create treatment plans for Cobalt-60 based systems. The Cobalt-60 based dose calculation, optimization, and sequencing algorithms present in CORVUS 2011 are very similar to those used in CORVUS 09 for Linacs. In addition to supporting CORVUS 09 Linac based treatment

plans and systems, CORVUS 2011 supports the following for Cobalt-60 based treatment planning solution:

- a. Theratron Equinox 100 Gamma Teletherapy System (Best Theratronics) (K053485)
- b. Avanza Couch/Patient Positioning Table (Best Theratronics) (K060870)
- c. NomosSTAT (Best Nomos) (K060895)
- d. Export of Cobalt-60 plans via nomosSTAT proprietary format and DICOM RT

In both the products (CORVUS 2011 (Linac and Cobalt-60) and CORVUS 09 (Linac)), the pencil-beam algorithm is used and dose calculation can be performed using either a homogeneous option or an Effective Path Length (EPL) option. The dose calculation based on the Lateral Disequilibrium Inclusive option (for Linacs in CORVUS 2011 and CORVUS 09) is not supported for the Cobalt-60 based planning option in CORVUS 2011. The optimization algorithms used in both cases are the same. The workflow in CORVUS 2011 for Gamma Tomotherapy when compared to its predicate device CORVUS 09 is unchanged.

To account for the larger, cylindrical source of the Cobalt-60 system and for radioactive source decay, the following modifications were made in CORVUS 2011 for Gamma Tomotherapy:

- i. During commissioning the calibration dose rate, the calibration date and the treatment start date for each patient needs to be specified. During commissioning the system performs a sanity check of the measured penumbra vs the calculated penumbra based on source size.
- ii. The pencil beam algorithm has been updated to account for source size in addition to accounting for radioactive source decay. The changes include modification to:
 - a. Primary Geometric Kernel to reflect large cylindrical cobalt source. The Radiological Kernel did not require any modification.
 - b. Account for large source when calculating scatter dose for small field sizes.
 - c. Account for leaf curvature interplay with the large source (fluence correction for the large source in sequencing algorithm).

For the gamma ray (Cobalt-60) based treatment planning for external beam therapy the CORVUS 2011 system shares many of the technological features and characteristics as that of the predicate device ViewRay Treatment Planning and Delivery System (K102915) for treatment planning. The target population and intended use are similar to that of the predicate devices. In addition, the fundamental technical characteristics are the same as those of the predicate devices and any minor differences in features do not raise any concerns for safety, performance, or effectiveness of the device. The characteristics/features of CORVUS 2011 with respect to each of the predicate devices is described in the comparison chart in the submission. The similarities and differences are discussed in detail as part of this submission.

M. SUMMARY OF PERFORMANCE TESTING

Activities to ensure that the modifications do not affect safety or effectiveness are provided in CORVUS 2011 Total Validation Report and CORVUS 2011 Verification Summary Report. The total validation activities included clinical workflow, treatment planning software

usability, clinical plan quality / optimization comparison, and dosimetric accuracy reports. The verification activities included system tests, module tests, anomaly verification, code review, linac dose equivalence report, and run-through integration tests.

Design verification and validation testing was performed to ensure that the device functionality for treatment planning works as per its intended use, is substantially equivalent with respect to its predicate device, all risks are mitigated, and the product conforms to the required standards. The details of the design verification and validation activities are explained in the submission (Section 15). The accuracy of treatment plans was evaluated through comparison with medical physics measurements including film and ion chamber measurements. The quality of treatment plans was evaluated based upon clinical criteria associated with conformal therapy.

CORVUS 2011, for Cobalt treatment planning, has been tested on and supports the following:

- a. Theratron Equinox 100 Gamma Teletherapy System (Best Theratronics) (K053485)
- b. Avanza Couch/Patient Positioning Table (Best Theratronics) (K060870)
- c. NomosSTAT (Best Nomos) (K060895)
 - i. Plan delivery to nomosSTAT is via NOMOS proprietary format: MIMiC Delivery File Set Specification.
- d. Export to R&V systems via DICOM RT defined by DICOM standard (tested on Mosaik version 2.3)
 - i. Corvus 2011 for Cobalt-60 planning uses the convention 1min = 100 MU in the treatment plan to export in DICOM RT format. This keeps the structure of the data the same as that used for exporting LINAC plans as defined by DICOM standard. However, for nomosSTAT plans, the DICOM RT plans do not contain the leaf positions as the MIMiC is a binary leaf MLC.

Summary of the tests performed, in addition to system testing, module testing, and clinical workflow testing, to ensure accuracy of treatment plans and clinical efficacy of CORVUS 2011 system include:

Sr. No.	Test	Test Details	Results
1.	Linac Dose Equivalence Test	To test Linac treatment plans for the same patients between CORVUS 09 and CORVUS 2011	The results showed that the Linac treatment plans recomputed (resegmented and redosed) with CORVUS 2011 had equivalent dose and sequences to those created on CORVUS 09.
2.	Clinical comparison of CORVUS 09 treatment plans with Cobalt treatment plans on CORVUS 2011	To test the clinical efficacy of treatment plans created for Cobalt treatment on CORVUS 2011 with respect to treatment plans created for Linac treatment on	The results showed that the treatment plans created for Cobalt based treatment were clinically acceptable and were comparable to Linac based treatment plans on CORVUS 09.

		CORVUS 09.	
3	Dosimetric Accuracy	To determine the dosimetric accuracy of the plans delivered to phantoms and measured using EDR2 film and 0.125 cc chamber	>95% of points pass relative comparison for all film. Chamber reading within 1.5% (pass/fail criteria of 4% / 4mm).
4	Comparison of calculated versus measured values	To determine if Cobalt based plans generate similar dose values as those measured using EDR2 films and CC01 ionization chamber	Multiple test results of dosimetric parameters (such as percentage dose depth and output factors for various pencil beam sizes) showed that the Cobalt plan based calculated values are similar to those measured using film and ion chambers. Output factors and percentage depth dose curves agreed within <4% (pass/fail criteria of 4% / 4mm).
5	Dose Comparisons for CORVUS 2011 using Gamma Tomotherapy	<ul style="list-style-type: none"> • Check for dose calculation consistency when there is a large growth region (margin) distinguishing PTV and CTV • Compare EPL (Effective Path Length Heterogeneity correction) and homogeneous calculation in a water equivalent phantom • Verify consistency of hybrid plans and patient plans • Check the consistency of single fraction hybrid plans and multi-fraction patient plans • Check the dose scaling feature • Check the decay calculations 	<p>The results indicated that:</p> <ul style="list-style-type: none"> • The growth margin does not affect the dose distribution. Profiles of the hybrid plan and the patient plan matched exactly for EPL and homogeneous calculation. • In a water equivalent phantom, EPL and homogeneous calculation matched as expected. • The statistics, treatment plan, and dose profiles of the hybrid plan match the original patient plan when the original plan is applied to its own geometry (for both EPL & homogeneous calculation options). • The dose to the chamber per fraction in the original multi-fraction plan and the hybrid calculation agree as expected. • Scaling the dose in Display Results using the “Total delivered dose” and “Percentage of Max Delivering XX Gy” boxed

			<p>changed the treatment time and mean chamber dose according as per expectations.</p> <ul style="list-style-type: none"> • The decay calculation agreed as expected.
6	Transfer to R&V System	To test transfer to Mosaiq record and verify system via Dicom RT	All fields including Energy, Field Size, Gantry Start Angle, Gantry Stop Angle, Collimator Angle, Couch Angle, and MU of each arc were verified to be correct.
7	Comparison of Linac plan Optimization	To compare the optimization of Linac plans in CORVUS 2011 with respect to CORVUS 09	Comparative analysis of the optimized plans (statistics, isodose distributions and dose volume histograms) indicated that these plans were clinically similar.
8	Final build – validating dose accuracy	To re-assess the dosimetric accuracy of CORVUS 2011 for all cobalt validation plans in the final build using EDR2 film	>98% of the points pass for all the plans (pass fail criteria of 4%/4mm)

Detailed results of these tests are included as part of this submission. The verification and validation results demonstrate that the CORVUS 2011 system met its design requirements and specifications, is substantially equivalent to its predicate device, is safe and effective to use for its intended purpose, and conforms to the applicable sections of standards that includes IEC 63204:2006: Medical device software – Software life cycle processes, BS EN 62366:2008: Medical devices -Application of usability engineering to medical devices, and IEC 62083:2009: Requirements for the safety of radiotherapy treatment planning systems.

Refer to Section 6 for the Declaration of Conformity.