Best Nomos
℅ Vineet Gupta, Ph.D.
Director - R&D
One Best Drive
PITTSBURGH PA 15202

September 20, 2020

Re: K201350
Trade/Device Name: CORVUS
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: August 21, 2020
Received: August 24, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201350

Device Name

CORVUS

Indications for Use *(Describe)*

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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K201350

510(k) Summary

A. SUBMITTERS NAME

Best NOMOS

B. ADDRESS

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D. DATE PREPARED

May 20, 2020

E. DEVICE NAME

Device Trade Name: **CORVUS**
Common Name: Radiation Therapy Treatment Planning System
Classification Name: Medical charged-particle radiation therapy system (21CFR 892.5050)

F. DEVICE CLASS

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

G. PREDICATE DEVICES

CORVUS Radiation Therapy Treatment Planning System 2011 (K151469)

H. STATEMENT OF INDICATIONS FOR USE

The intended use for the CORVUS Radiation Therapy Treatment Planning System has been updated to include the support for forward planning based treatment planning. The indications for use for the CORVUS Radiation Therapy Treatment Planning System has not changed due to this modification to the product. 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. For IMRT, 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. For Forward Planning, CORVUS helps the user manually create a plan for treatment delivery based on user supplied inputs and patient scans including dose calculation. Forward Planning is supported only for Cobalt-60 based treatment planning.

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 delivery device for planning and delivery of conformal radiation therapy. CORVUS produces radiation fields to conform to the projected tumor volume plus margins as desired during planning. The system provides statistical calculations to help 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.

I. DEVICE DESCRIPTION

CORVUS is a semi-automatic planning system: For forward planning, the system allows the user to design a treatment plan. For IMRT, 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.

J. PREDICATE DEVICE INFORMATION

The CORVUS 14 system is substantially equivalent to its primary predicate device CORVUS 2011 (K151469; Decision Date: 25-Nov-2015). The CORVUS 2011 system was determined to be substantially equivalent to its predicate device as of November 2015.

The fundamental scientific technology of the CORVUS 14 with respect to its predicate device (CORVUS 2011) system has not changed. The indications for use of the device has not changed. Based upon the performance testing results for CORVUS 14 (as detailed in the submission), the system raises no new issues of safety or effectiveness.

K. COMPARISON TO THE PREDICATE DEVICE

This section provides the summary of comparison of CORVUS 14 to the predicate device.

Table 1 Indications for Use & Intended Use Comparison

	Proposed Device **CORVUS 14**	**Predicate Device** **CORVUS 2011 (K151469)**
Intended Use	CORVUS is intended for use as a planning tool for conformal radiation therapy. For IMRT, 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. For Forward Planning, CORVUS helps the user manually create a plan for treatment delivery based on user supplied inputs and patient scans including dose calculation. Forward Planning is supported only for Cobalt-60 based treatment planning 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 delivery device for planning and delivery of conformal radiation therapy. CORVUS produces radiation fields to conform to the projected tumor volume plus margins as desired during planning. The system provides statistical calculations to help achieve target goals while sparing sensitive structures.	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	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.	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.

Table 2 General Comparison

Comparison Item	**Proposed Device CORVUS 14**	**Predicate Device CORVUS 2011 (K151469)**
Product Code	90-MUJ	90-MUJ
Class	II	II
Regulation Number	892.5050	892.5050
Operating System	Mac OS X	Mac OS X
Treatment Planning Support for X-Rays	MLC-IMRT, Serial Tomotherapy (MIMiC-IMRT)	MLC-IMRT, Serial Tomotherapy (MIMiC-IMRT)
Treatment Planning Support for Cobalt-60 (Gamma Rays)	Serial Tomotherapy (MIMiC-IMRT), MLC-IMRT, Forward Planning	Serial Tomotherapy (MIMiC-IMRT)

CORVUS 14 contains all of the features of CORVUS 2011 (K151469) and adds the feature of supporting Cobalt-60 based external beam radiation treatment planning based on IMRT and Forward Planning. The similarities and differences are discussed in detail as part of this submission.

In both products, CORVUS 14 and CORVUS 2011, 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 is only supported for X-Ray based treatment planning in CORVUS 14 as it was in the

predicate device CORVUS 2011 (K151469). The optimization algorithms used in both products are the same.

The target population and indications for 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 14 with respect to the predicate device is described in the comparison chart in the submission.

L. SUMMARY OF TESTING

Design verification and validation testing was performed to ensure that the device functionality works as per its intended use, all risks are mitigated, is substantially equivalent, and the product conforms to the required standards. The software for this device is considered as a "Major" level of concern. The details of the design verification and validation activities are explained in the submission as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The verification activities included system tests, module tests, anomaly verification, code reviews, and run-though integration tests.

The validation activities included clinical workflow, treatment planning software usability, clinical plan quality / optimization comparison, and dosimetric accuracy. The accuracy of treatment plans was evaluated through comparison with medical physics measurements including film and ion chamber measurements.

Conclusion:

Detailed results of these tests are included as part of this submission. The verification and validation results demonstrate that the CORVUS 14 system met its design requirements and specifications, is substantially equivalent to its predicate device, and conforms to the applicable sections of standards that includes:

- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
- IEC 62366-1 Edition 1.0 2020-06 Application of usability engineering to medical devices
- IEC 61217 Edition 2.0 2011-12 Radiotherapy equipment - Coordinates, movements, and scales
- IEC 62083 Edition 2.0 2009-09 Requirements for the safety of radiotherapy treatment planning systems