August 7, 2018

CNMC Co., Inc.
% Mr. Thomas Kraus
Vice President R&D
865 Easthagen Drive
NASHVILLE TN 37217

Re: K173848
Trade/Device Name: Model WP-3840 and WP-3040
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 2, 2018
Received: July 9, 2018

Dear Mr. Kraus:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

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

Enclosure

a Best Medical International company

Indications for Use Statement

510(k) Number (if known):__K173848_____

Device Name**:**

Model WP-3840 and WP-3040

Indication for Use:

The Water Phantom **WP-3840 and WP-3040** comprises of a one-dimensional precision mechanism attached to an Acrylic water tank. Various radiation detectors can be positioned along a vertical guide rail in different depths according to the application needs. The WP-3840 and WP-3040 consist of the basic acrylic water tank phantom, equipped with a hand crank to move the detector. That hand crank is coupled to a mechanical counter, reset-able position indicator that displays the depth.

Type of Use (Select one or both, as applicable) This devices is not used by individuals.

☒Prescription Use (Part 21 CFR 801 Subpart D)

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

CNMC Company Incorporated
865 Easthagen Drive
Nashville, Tennessee 37217

865 Easthagan Drive, Nashville, TN 37217
phone 615 391 3076 800 635 2662 fax 615 885 0285
www.cnmcco.com www.teambest.com

a Best Medical International company

510(k) Premarket Notification Summary (K173848)

CNMC Model WP-3840 and WP-3840

Submitter:	CNMC Company Incorporated 865 Easthagen Drive Nashville, Tennessee 37217
Contact:	Thomas Kraus Vice President R&D 615-391-3076 tkraus@cnmcco.com
Date:	July 2, 2018
Trade Names:	Model WP-3840 and WP-3040
Common Name:	1D Water Phantom
Classification Name:	Medical charged-particle radiation therapy system (21 CFR 892.5050)
Classification:	Class II
Product Code:	IYE
Substantial Equivalence:	The CNMC Model WP-3840 and WP-3040 is substantially equivalent to the Medtec, Inc. – K943199.
Description and Use:	The Water Phantom WP-3840 and WP-3040 comprises of a one-dimensional precision mechanism attached to an Acrylic water tank. Various radiation detectors can be positioned along a vertical guide rail in different depths according to the application needs. The WP-3840 and WP-3040 consist of the basic acrylic water tank phantom, equipped with a hand crank to move the detector. That hand crank is coupled to a mechanical counter, reset-able position indicator that displays the depth.
Intended Use:	The 1D Water Phantom WP-3840 and WP-3040 is used to position various radiation detectors in water or air. It consists of a cubic acrylic tank and a precision one-dimensional hand crank. By design it is suitable to act as a phantom according to various protocols such as the AAPM's TG-51protocol.

865 Easthagan Drive, Nashville, TN 37217
phone 615 391 3076 800 635 2662 fax 615 885 0285
www.cnmcco.com www.teambest.com

Similarities/Differences of the CNMC Model WP3840/WP3040 to their predicate device:

	Model WP-3840/WP-3040	Model MT-150
How the device is used.	The Water Phantom WP-3840 and WP-3040 comprises of a one-dimensional precision mechanism attached to an Acrylic water tank. Various radiation detectors can be positioned along a vertical guide rail in different depths according to the application needs.	The MT-150 is a 1D stand-alone water phantom for absolute dose measurements according to TG-51 and IAEA TRS-398 dosimetry protocols.
Intended use	Radiation dosimetry	Radiation dosimetry
Detectors	ion chambers, diodes	ion chambers, diodes
Manual Control	Yes	Yes
Travel Range	0 – 25cm	0 – 25cm
Resolution	0.1mm	0.1mm
Position Indicator	Yes (Mechanical)	Yes (Mechanical)
Position Indicator Resettable	Yes	Yes
Acrylic Tank Dimensions	WP3840: 38cm W x 40cm L x 38cm H WP3040: 30cm W x 40cm L x 38cmH	38cm W x 38cm L x 38cm H 30.5cm W x 38cm Lx 38cm H
Drain Valve	Yes	Yes

Brief Comparison: Both the predicate device and the WP-3840/WP-3040 have been developed for use per AAPM TG-51 protocol. Both devices are manufactured from the exact material. Both devices use a manual hand crank for positioning the detectors to the desired position. Both devices have a mechanical counter to give the position of the detector.

Conclusion: The model WP-3840 and WP-3040 is substantially equivalent to the predicate device for the following reasons:

1. The indication for use of the Model WP-3840 and WP-3040 is exactly the same as the predicate device.
2. The units are very similar in design.
3. The Model WP-3840/WP-3040 and the predicate device are used for the same protocol.
4. The Model WP-3840/WP-3040 and the predicate device uses the same material for manufacturing
5. CNMC considers the Model WP-3840/WP-3040 equivalent in all areas to the predicate device.

865 Easthagan Drive, Nashville, TN 37217
phone 615 391 3076 800 635 2662 fax 615 885 0285
www.cnmcco.com www.teambest.com