MEDTEC, Inc. dba CIVCO Medical Solutions
and CIVCO Radiotherapy
℅ Ms. Alena Newgren
Regulatory Manager
1401 8th Street SE
ORANGE CITY IA 51041

May 20, 2021

Re: K211001
Trade/Device Name: C-Qual M™ Breastboard; Monarch™ Overhead Arm Positioner
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE, LNH
Dated: March 31, 2021
Received: April 2, 2021

Dear Ms. Newgren:

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 and Part 809); 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211001

Device Name
C-Qual M Breastboard with Monarch Overhead Arm Positioner

Indications for Use *(Describe)*
The device is indicated to aid in supporting and positioning adult and adolescent patients undergoing radiation therapy of the breast and chest region including electron, photon, and proton treatments. Device is also used to position the patient during image acquisition to support treatment planning including in Computed Tomography (CT) and Magnetic Resonance (MR) imaging systems. The device is not intended for use with patients under 12 years of age.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K211001

A. Submitter Information

Submitter Name & Address:	MEDTEC, Inc. d/b/a "CIVCO Medical Solutions" and "CIVCO Radiotherapy" 1401 8th St. SE Orange City, IA 51041
Contact Person:	Alena Krishna, Regulatory Affairs Manager Telephone: 319-248-6650 Alena.Newgren@civcort.com
Date Summary Prepared:	March 31, 2021
Trade Names:	C-Qual M™ Breastboard; Monarch™ Overhead Arm Positioner
Common Names:	Breastboard; Overhead Arm Positioner
Classification Names & Numbers:	Medical charged-particle radiation therapy system (892.5050) System, Nuclear Magnetic Resonance Imaging (892.1000)
Device Class:	Class II
Review Panels:	Radiology
Product Codes:	IYE, LNH

B. Predicate Devices

The Breastboard and Overhead Arm Positioner are substantially equivalent to the following predicate device:

Predicate Device	Manufacturer
K180021: Proton Positioning and Immobilization Devices (Breast Devices)	CIVCO Radiotherapy

The purpose of this 510(k) is to add MR to the indications for use for the MTM410.

C. Device Descriptions

The Breastboard and Overhead Arm Positioner are used to position the patient during external beam radiation therapy. The Breastboard is comprised of a Base, Back Support, and Bottom Stop. The Base serves as the foundation of the assembly and provides a mounting surface for the Back Support, Angle Supports, and the Bottom Stop. The inferior end of the Back Support

is mounted to the Base while the superior end of the Back Support is raised/lowered as needed for patient setup using Low Angle or High Angle Supports. The Bottom Stop is located near the inferior end of the Base and prevents the patient from sliding down the Board.

The Low Angle Support is used to position the Back Support at 5°, 7.5°, 10°, 12.5°, and 15° angles. Features on the High Angle Support receive the cutouts on the Low Angle Support and hold the angular position of the Support.

The High Angle Support is used to position the Back Support at 17.5°, 20°, 22.5°, and 25° angles. Features on the Base receive the cutouts on the High Angle Support and hold the angular position of the Support.

A Lock provides a method of locking the Back Support to the Base at 0° to facilitate easier handling and storage of the Breastboard.

The Overhead Arm Positioner provides support for the patient's arms above the head and is attached to the Back Support via a locking assembly. The Overhead Arm Positioner adjusts longitudinally on the Back Support to accommodate a variety of patient sizes. A Hand Grip is mounted on the Overhead Arm Positioner and the location of the Hand Grip is adjustable longitudinally.

A Head Support rests on a recessed area of the Overhead Arm Positioner and provides a cushion for positioning of the head of the patient. The Head Support can also be mounted directly on the Breastboard. A Thermoplastic Frame may also be mounted to the Overhead Arm Positioner to enable attachment of a thermoplastic mask for additional patient support.

The Breastboard and Overhead Arm Positioner can also be used for supporting and elevating patients undergoing treatment who cannot lay down flat on the table due to their habitus.

The Breastboard and Overhead Arm Positioner are reusable devices that are provided non-sterile. The devices are used in a healthcare facility/hospital. The following model is included in this submission:

Part No.	**Device Name**
MTM410	C-Qual MR™ Breastboard and Monarch™ Overhead Arm Positioner

D. Indications for Use/Intended Use Statements

Indications for Use/Intended Use: The device is indicated to aid in supporting and positioning adult and adolescent patients undergoing radiation therapy of the breast and chest region including electron, photon, and proton treatments. Device is also used to position the patient during image acquisition to support treatment planning including in Computed Tomography

(CT) and Magnetic Resonance (MR) imaging systems. The device is not intended for use with patients under 12 years of age.

E. Comparison of Technological Characteristics

There are no technological differences between the predicate and proposed device. Both the proposed and predicate Breastboard are comprised of a Base, Back Support, and Bottom Stop. Both devices consist of High Angle and Low Angle Supports that allow elevation from 5 to 25° in 2.5 degree increments. The Overhead Arm Positioner adjusts longitudinally on the Back Support via a locking assembly.

F. Non-Clinical Testing

To add MR indications to the Breastboard and Overhead Arm Positioner (MTM410), the device was tested for MR safety and compatibility in accordance with ASTM Standard F2052-15. Testing was also completed using ASTM Standards F2213-06 and F2119-07 as guidance. The device passed the acceptance criteria for magnetically induced torque and magnetically induced displacement force and demonstrate that the device is safe for use in field strengths of 1.5 T and 3.0 T. Image artifact was observed, with the worst case artifact occurring near the location of the locking knob on the Breastboard. Information regarding size of this artifact has been included in the Instructions for Use. In addition to MR safety testing, other non-clinical testing demonstrated that the differences in technological characteristics did not raise any new issues of safety or effectiveness.

Biocompatibility testing was completed for patient-contacting materials in accordance with ISO 10993-5:2009 and ISO 10993-10:2010. The Breastboard and Overhead Arm Positioner is intended for limited contact duration (<24 hours) for surface devices (skin).

G. Conclusion

This premarket submission for the Breastboard and Overhead Arm Positioner has demonstrated substantial equivalence as defined and understood in the Federal Food, Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.