MEDTEC, Inc. d/b/a "CIVCO Medical Solutions" and "CIVCO Radi
% Ms. Alena Newgren
Regulatory Specialist
140 l 8th Street SE
ORANGE CITY IOWA 51041

June 29, 2018

Re: K180021
Trade/Device Name: Proton Positioning and Immobilization Devices
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: December 22, 2017
Received: January 3, 2018

Dear Ms. Alena:

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.

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,

For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K180021

Device Name
General Positioning Devices; Head, Neck, and Shoulders Devices; Support Garments; Breast Positioning Devices

Indications for Use *(Describe)*
General Positioning Devices: The device is indicated to aid in supporting and positioning adult and pediatric patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. Devices include Couchtops, Lok-Bars, Extensions, Cushions, and Accessories. The following are other positioning devices:

Head, Neck, and Shoulders Devices: The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. Devices include Overlays, Extensions, Thermoplastic Masks, and Cushions.

Support Garments: The device is indicated to aid in supporting adolescent and adult patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. The device is not intended for use with patients under 12 years of age.

Breast Positioning Devices: 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. The device is also used during image acquisition to support treatment planning. 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.

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510(k) Summary

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 Newgren, Regulatory Specialist Telephone: 712-737-8688, Fax: 877-613-6300 regulatory@civcort.com
Date Summary Prepared:	June 13, 2018
Trade Name:	Proton Positioning and Immobilization Solutions
Common Name:	Head, Neck and Shoulders Devices General Positioning Devices Support Garments Breast Positioning Devices
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 subject devices are substantially equivalent to the predicate devices in the following 510(k)s:

Predicate Device:	**Manufacturer**
K973842: Carbon Fiber Conformal Couch Top	MEDTEC, Inc.
Reference Devices:	
K933227: Uni-Frame Head Immobilization System	
K080072: MRI Patient Positioning Devices	
K060737: Sinmed Positioning Devices	
K982624: Moldcare Head & Neck Cushion	
K935300: Vac-Lok Immobilization System	
K121284: Chabner XRT Garments	
K974703: Carbon Fiber Breast Board	

The purpose of this 510(k) is to modify the intended use/indications for use for the subject devices including specification of proton treatment and pediatric/adolescent use.

D. Device Descriptions

This submission does not include in-vitro diagnostic devices.

The CIVCO Positioning and Immobilization devices have been used for many years and were previously cleared under other 510(k)'s. This 510(k) is to have these identical Class II products cleared for use in Proton Therapy environment.

The Head, Neck, and Shoulder Devices are used to treat cancer of the head, neck, brain and spine. Organs that are located in these anatomical regions are applicable.

The General Positioning Devices are used to treat cancer of the spine, thorax, breast, abdomen, pelvis and prostate. Organs that are located in these anatomical regions are applicable.

The Support Garments are used to treat cancer of the breast, thorax and abdominal area. Organs that are located in these anatomical regions are applicable.

The Breast Positioning Devices are used to treat cancer of the breast, thorax and abdominal area. Organs that are located in these anatomical regions are applicable.

The devices are intended for therapeutic treatment (including proton, photon, and electron beam therapy) and diagnostics (including CT and MR as indicated). The devices will be used in a variety of types of external beam radiation therapy including Intensity Modulated Proton Therapy (IMPT), Intensity Modulated Radiation Therapy (IMRT), Pencil Beam Proton Therapy (PBPT), Image Guided Radiation Therapy (IGRT), Volumetric Modulated Arc Therapy (VMAT), Stereotactic Radiosurgery (SRS), Stereotactic Radiotherapy (SRT), Stereotactic Body Radiation Therapy (SBRT), and Craniospinal Treatment.

The intended users of the devices are radiation oncology therapists, medical physicists, and oncologists. The provider selects the appropriate equipment based on a patient's individual clinical goals and unique constraints.

Thermoplastic mask, AccuForm Cushion, and Support Garment devices are single patient use. All devices are non-powered and static. Detailed device specific descriptions are located in Section 11.

The subject devices are reusable or disposable as provided in product labeling, provided non-sterile, and are used in a healthcare facility/hospital. The devices are labeled for MR safety, as applicable. The following models are included in this submission:

Table A. Head, Neck, and Shoulders Devices.

Device Family	Part No.	Device Name	Reference 510(k)
Overlay	MTPT210002	Type-S™ Overlay (Reusable non-sterile overlay with thermoplastic frame for use with Hitachi proton system)	K933227
	MTMRHNTYPES	Type-S™ Overlay (Reusable non-sterile Type-S™ overlay with strap)	K080072
Thermoplastic Mask	MTAPUDMP	Disposable non-sterile head only FirmFit™ Thermoplastic (2.3mm)	K060737
	MTAPSDMP	Disposable non-sterile head neck, and shoulder FirmFit™ Thermoplastic (2.3mm)	
	MTAPUDMPSG	Disposable non-sterile head only open face FirmFit™ Thermoplastic (2.3mm)	
Extension	MTPT210001	Type-S™ Extension (Reusable non-sterile head extension for use with Hitachi proton system)	K933227
	MTIL6665	Type-S Extension (Reusable non-sterile extension for use with Universal Couchtop Long Extension)	K973842
	MTIL6668	SRS Posifix Extension (Reusable non-sterile SRS compatible extension for use with Universal Couchtop Long Extension)	K973842
Cushion	MTACL1520	AccuForm™ Cushion (15 x 20 cm)	K982624 and K080072
	MTACL2035	AccuForm™ Cushion (20 x 35 cm) chamfered	
	MTACL2035HF	AccuForm™ Cushion (20 x 35 cm) chamfered, half fill	
	MTACL2045	AccuForm™ Cushion (20 x 45 cm)	
	MTACL4060	AccuForm™ Cushion (40 x 60 cm)	
	MTACL6060	AccuForm™ Cushion (60 x 60 cm)	
	MTACL14242	AccuForm™ Cushion (20 x 25 cm)	
	MTACLTYPES1	AccuForm™ Cushion (Types-S)	

Table B. General Positioning Devices.

Couchtop & Lok-Bar	MTIL6720	IPPS™ Couchtop (Reusable non-sterile one piece couchtop with Lok-Bar)	K973842
	MTIL6740	Universal Couchtop (Reusable non-sterile couchtop with Lok-Bar, rectangular extension, and storage rack)	
Extension	MTIL6660	Rectangular Extension (Reusable non-sterile rectangular extension for use with Universal Couchtop Long Extension)	K973842
Accessories (Hand Grips)	MTIL662501	Patient Hand Grip (Reusable non-sterile SBRT Body Pro-Lok™ hand grip (right) for use with Universal Couchtop)	K973842
	MTIL662502	Patient Hand Grip (Reusable non-sterile SBRT Body Pro-Lok™ hand grip (left) for use with Universal Couchtop)	
Cushion (Vac-Lok)	MTVLG35FC	Vac-Lok ™ Cushion (Reusable, non-sterile, 70 x 100 cm, 35L, nylon bag with indexing safe for use in 1.5T and 3.0T MR environments)	K080072 K935300
Cushion (Combifix)	151004	Combifix™ (Reusable non-sterile Combifix™ baseplate with (2) elevation blocks, Feetfix™ bracket, Feetfix cushion, and Kneefix™ cushion)	K060737

Table C. Support Garments

Support Garments (Brassiere)	CRTBRA01	Chabner XRT® Radiation Bra, Size 1	K121284
	CRTBRA02	Chabner XRT® Radiation Bra, Size 2	
	CRTBRA03	Chabner XRT® Radiation Bra, Size 3	
	CRTBRA04	Chabner XRT® Radiation Bra, Size 4	
	CRTBRA05	Chabner XRT® Radiation Bra, Size 5	
	CRTBRA06	Chabner XRT® Radiation Bra, Size 6	
	CRTBRA07	Chabner XRT® Radiation Bra, Size 7	
	CRTBRA08	Chabner XRT® Radiation Bra, Size 8	
	CRTBRA09	Chabner XRT® Radiation Bra, Size 9	
	CRTEXT01	Bra Extender	

Table D. Breast Positioning Devices

Breastboard	MTM400	C-Qual™ (Reusable non-sterile breastboard with head support and Monarch™ Overhead Arm Positioner)	K080072

E. Indications for Use/Intended Use Statements

General Positioning Devices:
The device is indicated to aid in supporting and positioning adult and pediatric patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. Devices include Couchtops, Lok-Bars, Extensions, Cushions, and Accessories. The following are other positioning devices:

Head, Neck, and Shoulder Devices:
The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. Devices include Overlays, Extensions, Thermoplastic Masks, and Cushions.

Support Garments:
The device is indicated to aid in supporting adolescent and adult patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. The device is not intended for use with patients under 12 years of age.

Breast Positioning Devices:
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. The device is also used during image acquisition to support treatment planning. The device is not intended for use with patients under 12 years of age.

F. Comparison of Technological Characteristics

This 510(k) is being submitted only to add the Proton Intended Use and pediatric/adolescent use for these previously cleared devices.

Head, Neck, and Shoulders Devices

MTPT210002	Type-S™ Overlay		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K933227
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	The intended use of this device is to immobilize the head during radiation therapy.
Design Features	The Type-S Overlay is placed on top of the treatment table via Lok-Bar and allows for attachments of head or head, neck, and shoulders thermoplastic masks. The Overlay also allows a headrest to be used. The	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The baseplate sets on the treatment table and allows for attachments of head or head, neck, and shoulders thermoplastic masks. The baseplate also allows a headrest to be used. The baseplate is fitted with two registration pins that index to

	Overlay has holes that correspond to thermoplastic mask attachment pins.		corresponding holes in the thermoplastic frame to give precision repositioning. Four swivel clamps allow quick lock down and removal of the thermoplastic frame.
Principle of Operation	Mechanical devices without the use of software or electronics.		
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).		
Sterility	N/A Devices are non-sterile		

MTPT210001	Type-S™ Extension		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K933227
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	The intended use of this device is to immobilize the head during radiation therapy.
Design Features	The device attaches to the end of the treatment table via a cantilever lock and pin mechanism. The Extensions allows for the placement of a headrest and has corresponding holes for thermoplastic mask attachment of head only or head, neck, and shoulders.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The baseplate sets on the treatment table and allows for attachments of head or head, neck, and shoulders thermoplastic masks. The baseplate also allows a headrest to be used. The baseplate is fitted with two registration pins that index to corresponding holes in the thermoplastic frame to give precision repositioning. Four swivel clamps allow quick lock down and removal of the thermoplastic frame.

Principle of Operation	Mechanical devices without the use of software or electronics.
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).
Sterility	N/A Devices are non-sterile

MTMRHNTYPES	Type-S™ Overlay		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K080072
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Patient Positioning Devices are used to aid in the support and positioning of patients during an MRI.
Design Features	The Overlay is attached to the treatment couch top via Lok-Bar and secured by a Velcro strap. The overlay is contoured to follow the anatomy of the head, neck, and shoulder region by a 'S' shape. The Overlay contains holes for thermoplastic mask to attach to in either head only or head, neck, and shoulder style. A headrest can be placed on the Overlay for patient positioning and comfort.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is attached to the treatment pedestal via Lok-Bar and allows attachment of other positioning and immobilization devices or to be used stand-alone. The device allows a headrest to be added and thermoplastic masks to be attached.
Principle of Operation	Mechanical devices without the use of software or electronics.		
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).		
Sterility	N/A Devices are non-sterile		

MTAPUDMP	Disposable non-sterile head only FirmFit™ Thermoplastic			
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**	**Reference Device**
510k	K180021	K973842	K080072	K060737
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Patient Positioning Devices are used to aid in the support and positioning of patients during an MRI.	Fixation and (re)positioning of the head- and neck area of the patient during radiotherapy and diagnostics.
Design Features	Thermoplastic Masks are composed of a frame, mask, and push pins. The thermoplastic mask is submerged in heated water to soften. Once removed from the water, the user quickly dries off the water and then forms the mask around the patient's head and locks the pins into pinholes of the Couchtop, Extension, or Overlay. The SnapFrame style allows the user to pull the sides down first and then connect the top portion with the sides to make a continuous U-shaped frame.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	Thermoplastic Masks are composed of a frame, mask, and push pins. The thermoplastic mask is submerged in heated water to soften. Once removed from the water, the user quickly dries off the water and then forms the mask around the patient's head and locks the pins into pinholes of the Couchtop, Extension, or Overlay.	Thermoplastic Masks are composed of a frame, mask, and push pins. The thermoplastic mask is submerged in heated water to soften. Once removed from the water, the user quickly dries off the water and then forms the mask around the patient's head and locks the pins into pinholes of the Couchtop, Extension, or Overlay.
Principle of Operation	Mechanical devices without the use of software or electronics.	Mechanical devices without the use of	Mechanical devices without the use of software or electronics.	Mechanical devices without the use of software or electronics.

		software or electronics.		
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).	Limited contact duration (<24 hours) for surface devices (skin).	Limited contact duration (<24 hours) for surface devices (skin).	Limited contact duration (<24 hours) for surface devices (skin).
Sterility	N/A Devices are non-sterile	N/A Devices are non-sterile	N/A Devices are non-sterile	N/A Devices are non-sterile

MTAPSDMP	Disposable non-sterile head neck, and shoulder FirmFit™ Thermoplastic			
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**	**Reference Device**
510k	K180021	K973842	K080072	K060737
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	The intended use of this device is to provide an additional aid to the fast and accurate repeat positioning of the patient for radiation or other treatment.	Fixation and (re)positioning of the head- and neck area of the patient during radiotherapy and diagnostics.
Design Features	Thermoplastic Masks are composed of a frame, mask, and push pins. The thermoplastic mask is submerged in heated water to soften. Once removed from the water, the user quickly dries off the water and then forms the mask around the patient's head and locks the pins into pinholes of the Couchtop, Extension, or Overlay. The SnapFrame style allows the user to pull the	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	Thermoplastic Masks are composed of a frame, mask, and push pins. The thermoplastic mask is submerged in heated water to soften. Once removed from the water, the user quickly dries off the water and then forms the mask around the patient's head and locks the pins into pinholes of the Couchtop, Extension, or Overlay.	Thermoplastic Masks are composed of a frame, mask, and push pins. The thermoplastic mask is submerged in heated water to soften. Once removed from the water, the user quickly dries off the water and then forms the mask around the patient's head and locks the pins into pinholes of the Couchtop, Extension, or Overlay.

	sides down first and then connect the top portion with the sides to make a continuous U-shaped frame.			
Principle of Operation	Mechanical devices without the use of software or electronics.			
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).			
Sterility	N/A Devices are non-sterile			

MTAPUDMPSG	Disposable non-sterile head only open face FirmFit™ Thermoplastic			
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**	**Reference Device**
510k	K180021	K973842	K982624	K060737
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	The intended use of this device is to provide an additional aid to the fast and accurate repeat positioning of the patient for radiation or other treatment.	Fixation and (re)positioning of the head- and neck area of the patient during radiotherapy and diagnostics.
Design Features	Thermoplastic Masks are composed of a frame, mask, and push pins. The thermoplastic mask is submerged in heated water to soften. Once removed from the water, the user quickly dries off the water and then forms the mask around the patient's head and locks the	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	Thermoplastic Masks are composed of a frame, mask, and push pins. The thermoplastic mask is submerged in heated water to soften. Once removed from the water, the user quickly dries off the water and then	Thermoplastic Masks are composed of a frame, mask, and push pins. The thermoplastic mask is submerged in heated water to soften. Once removed from the water, the user quickly dries off the water and then forms

	pins into pinholes of the Couchtop, Extension, or Overlay. The SnapFrame style allows the user to pull the sides down first and then connect the top portion with the sides to make a continuous U-shaped frame.		forms the mask around the patient's head and locks the pins into pinholes of the Couchtop, Extension, or Overlay.	the mask around the patient's head and locks the pins into pinholes of the Couchtop, Extension, or Overlay.
Principle of Operation	Mechanical devices without the use of software or electronics.			
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).			
Sterility	N/A Devices are non-sterile			

MTIL6665	Type-S Extension	
Component/ Parameter	**Proposed Device**	**Predicate Device**
510k	K180021	K973842
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.
Design Features	The Type-S Extension attaches to the Couchtop junction outside of the treatment zone and is shaped so that it follows the contours of the patient's head, neck, and shoulder outline. Extensions do not require a support mechanism that needs to be moved or accounted for during planning and treatment.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.
Principle of Operation	Mechanical devices without the use of software or electronics.	
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).	
Sterility	N/A Devices are non-sterile	

MTIL6668	SRS Posifix Extension	
Component/ Parameter	**Proposed Device**	**Predicate Device**
510k	K180021	K973842
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.
Design Features	The Extension attaches to the Couchtop junction outside of the treatment zone and is shaped so that it follows the contours of the patient's head, neck, and shoulder outline. Extensions do not require a support mechanism that needs to be moved or accounted for during planning and treatment.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.
Principle of Operation	Mechanical devices without the use of software or electronics.	
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).	
Sterility	N/A Devices are non-sterile	

MTACL1520	AccuForm™ Cushion			
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**	**Reference Device**
510k	K180021	K973842	K080072	K982624
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Patient Positioning Devices are used to aid in the support and positioning of patients during an MRI.	The intended use of this device is to provide an additional aid to the fast and accurate repeat positioning of the patient for radiation or other treatment.
Design Features	AccuForm Cushions are activated by a chemical	The Couch Top is placed onto the	The device is attached to the	AccuForm Cushions are

	reaction when water is introduced to the inside materials. After the device has hardened it is a custom fit to the patient and can be used over the course of treatment.	treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	treatment pedestal via Lok-Bar and allows attachment of other positioning and immobilization devices or to be used stand-alone. The device allows a headrest to be added and thermoplastic masks to be attached.	activated by a chemical reaction when water is introduced to the inside materials. After the device has hardened it is a custom fit to the patient and can be used over the course of treatment.
Principle of Operation	Mechanical devices without the use of software or electronics.			
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).			
Sterility	N/A Devices are non-sterile			

MTACL2035	AccuForm™ Cushion			
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**	**Reference Device**
510k	K180021	K973842	K080072	K982624
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Patient Positioning Devices are used to aid in the support and positioning of patients during an MRI.	The intended use of this device is to provide an additional aid to the fast and accurate repeat positioning of the patient for radiation or other treatment.
Design Features	The Extension attaches to the Couchtop junction outside of the treatment zone and is shaped so that it follows the contours of the patient's head, neck, and	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to	The device is attached to the treatment pedestal via Lok-Bar and allows attachment of other positioning and immobilization	AccuForm Cushions are activated by a chemical reaction when water is introduced to the inside materials.

	shoulder outline. Extensions do not require a support mechanism that needs to be moved or accounted for during planning and treatment.	allow for patient positioning and immobilization.	devices or to be used stand-alone. The device allows a headrest to be added and thermoplastic masks to be attached.	After the device has hardened it is a custom fit to the patient and can be used over the course of treatment.
Principle of Operation	Mechanical devices without the use of software or electronics.			
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).			
Sterility	N/A Devices are non-sterile			

MTACL2035HF	AccuForm™ Cushion			
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**	**Reference Device**
510k	K180021	K973842	K080072	K982624
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Patient Positioning Devices are used to aid in the support and positioning of patients during an MRI.	The intended use of this device is to provide an additional aid to the fast and accurate repeat positioning of the patient for radiation or other treatment.
Design Features	The Extension attaches to the Couchtop junction outside of the treatment zone and is shaped so that it follows the contours of the patient's head, neck, and shoulder outline. Extensions do not require a support mechanism that needs to be moved or	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is attached to the treatment pedestal via Lok-Bar and allows attachment of other positioning and immobilization devices or to be used stand-alone. The device allows a headrest to be added and thermoplastic	AccuForm Cushions are activated by a chemical reaction when water is introduced to the inside materials. After the device has hardened it is a custom fit to the patient and can be used over the

	accounted for during planning and treatment.		masks to be attached.	course of treatment.
Principle of Operation	Mechanical devices without the use of software or electronics.			
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).			
Sterility	N/A Devices are non-sterile			

MTACL2045	AccuForm™ Cushion			
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**	**Reference Device**
510k	K180021	K973842	K080072	K982624
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Patient Positioning Devices are used to aid in the support and positioning of patients during an MRI.	The intended use of this device is to provide an additional aid to the fast and accurate repeat positioning of the patient for radiation or other treatment.
Design Features	The Extension attaches to the Couchtop junction outside of the treatment zone and is shaped so that it follows the contours of the patient's head, neck, and shoulder outline. Extensions do not require a support mechanism that needs to be moved or accounted for during planning and treatment.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is attached to the treatment pedestal via Lok-Bar and allows attachment of other positioning and immobilization devices or to be used stand-alone. The device allows a headrest to be added and thermoplastic masks to be attached.	AccuForm Cushions are activated by a chemical reaction when water is introduced to the inside materials. After the device has hardened it is a custom fit to the patient and can be used over the course of treatment.
Principle of Operation	Mechanical devices without the use of software or electronics.			

Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).
Sterility	N/A Devices are non-sterile

MTACL4060	AccuForm™ Cushion			
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**	**Reference Device**
510k	K180021	K973842	K080072	K982624
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Patient Positioning Devices are used to aid in the support and positioning of patients during an MRI.	The intended use of this device is to provide an additional aid to the fast and accurate repeat positioning of the patient for radiation or other treatment.
Design Features	The Extension attaches to the Couchtop junction outside of the treatment zone and is shaped so that it follows the contours of the patient's head, neck, and shoulder outline. Extensions do not require a support mechanism that needs to be moved or accounted for during planning and treatment.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is attached to the treatment pedestal via Lok-Bar and allows attachment of other positioning and immobilization devices or to be used stand-alone. The device allows a headrest to be added and thermoplastic masks to be attached.	AccuForm Cushions are activated by a chemical reaction when water is introduced to the inside materials. After the device has hardened it is a custom fit to the patient and can be used over the course of treatment.
Principle of Operation	Mechanical devices without the use of software or electronics.	Mechanical devices without the use of software or electronics.	Mechanical devices without the use of software or electronics.	Mechanical devices without the use of software or electronics.

Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).	Limited contact duration (<24 hours) for surface devices (skin).	Limited contact duration (<24 hours) for surface devices (skin).	Limited contact duration (<24 hours) for surface devices (skin).
Sterility	N/A Devices are non-sterile	N/A Devices are non-sterile	N/A Devices are non-sterile	N/A Devices are non-sterile

MTACL6060	AccuForm™ Cushion			
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**	**Reference Device**
510k	K180021	K973842	K080072	K982624
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Patient Positioning Devices are used to aid in the support and positioning of patients during an MRI.	The intended use of this device is to provide an additional aid to the fast and accurate repeat positioning of the patient for radiation or other treatment.
Design Features	The Extension attaches to the Couchtop junction outside of the treatment zone and is shaped so that it follows the contours of the patient's head, neck, and shoulder outline. Extensions do not require a support mechanism that needs to be moved or accounted for during planning and treatment.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is attached to the treatment pedestal via Lok-Bar and allows attachment of other positioning and immobilization devices or to be used stand-alone. The device allows a headrest to be added and thermoplastic masks to be attached.	AccuForm Cushions are activated by a chemical reaction when water is introduced to the inside materials. After the device has hardened it is a custom fit to the patient and can be used over the course of treatment.
Principle of Operation	Mechanical devices without the use of software or electronics.			
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).			

Sterility	N/A Devices are non-sterile

MTACL14242	AccuForm™ Cushion			
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**	**Reference Device**
510k	K180021	K973842	K080072	K982624
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Patient Positioning Devices are used to aid in the support and positioning of patients during an MRI.	The intended use of this device is to provide an additional aid to the fast and accurate repeat positioning of the patient for radiation or other treatment.
Design Features	The Extension attaches to the Couchtop junction outside of the treatment zone and is shaped so that it follows the contours of the patient's head, neck, and shoulder outline. Extensions do not require a support mechanism that needs to be moved or accounted for during planning and treatment.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is attached to the treatment pedestal via Lok-Bar and allows attachment of other positioning and immobilization devices or to be used stand-alone. The device allows a headrest to be added and thermoplastic masks to be attached.	AccuForm Cushions are activated by a chemical reaction when water is introduced to the inside materials. After the device has hardened it is a custom fit to the patient and can be used over the course of treatment.
Principle of Operation	Mechanical devices without the use of software or electronics.	Mechanical devices without the use of software or electronics.	Mechanical devices without the use of software or electronics.	Mechanical devices without the use of software or electronics.
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).	Limited contact duration (<24 hours) for surface devices (skin).	Limited contact duration (<24 hours) for surface devices (skin).	Limited contact duration (<24 hours) for surface devices (skin).

Sterility	N/A Devices are non-sterile	N/A Devices are non-sterile	N/A Devices are non-sterile	N/A Devices are non-sterile

MTACLTYPES1	AccuForm™ Cushion			
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**	**Reference Device**
510k	K180021	K973842	K080072	K982624
Intended Use/ Indications for Use	The device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery and electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Patient Positioning Devices are used to aid in the support and positioning of patients during an MRI.	The intended use of this device is to provide an additional aid to the fast and accurate repeat positioning of the patient for radiation or other treatment.
Design Features	The Extension attaches to the Couchtop junction outside of the treatment zone and is shaped so that it follows the contours of the patient's head, neck, and shoulder outline. Extensions do not require a support mechanism that needs to be moved or accounted for during planning and treatment.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is attached to the treatment pedestal via Lok-Bar and allows attachment of other positioning and immobilization devices or to be used stand-alone. The device allows a headrest to be added and thermoplastic masks to be attached.	AccuForm Cushions are activated by a chemical reaction when water is introduced to the inside materials. After the device has hardened it is a custom fit to the patient and can be used over the course of treatment.
Principle of Operation	Mechanical devices without the use of software or electronics.			
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).			
Sterility	N/A Devices are non-sterile			

General Positioning Devices

MTIL6720	IPPS™ Couchtop	
Component/ Parameter	**Proposed Device**	**Predicate Device**
510k	K180021	K973842
Intended Use/ Indications for Use	The device is indicated to aid in supporting and positioning adult and pediatric patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.
Design Features	The Couchtop is attached to a treatment delivery system pedestal. The Couchtop uses Prodigy 2 indexing at seven centimeter increments to allow indexing for accessories to be attached which allows patient positioning and immobilization.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.
Principle of Operation	Mechanical devices without the use of software or electronics.	
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).	
Sterility	N/A Devices are non-sterile	

MTIL6740	Universal Couchtop	
Component/ Parameter	**Proposed Device**	**Predicate Device**
510k	K180021	K973842
Intended Use/ Indications for Use	The device is indicated to aid in supporting and positioning adult and pediatric patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.
Design Features	The Couchtop is attached to a treatment delivery system pedestal. The Couchtop uses Prodigy 2 indexing at seven centimeter increments	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.
Principle of Operation	Mechanical devices without the use of software or electronics.	
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).	
Sterility	N/A Devices are non-sterile	

MTIL6660	Rectangular Extension	
Component/ Parameter	**Proposed Device**	**Predicate Device**
510k	K180021	K973842
Intended Use/ Indications for Use	The device is indicated to aid in supporting and positioning adult and pediatric patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.
Design Features	The Rectangular Extension attaches to a Couchtop junction, outside of the treatment zone, and is shaped to allow a variety of treatment areas. The patient lays on top of the device while receiving treatment. The Rectangular Extension has seven-centimeter indexing to allow for reproducible patient positioning with accessory devices.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.
Principle of Operation	Mechanical devices without the use of software or electronics.	
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).	
Sterility	N/A Devices are non-sterile	

MTIL662501	Patient Hand Grip	
Component/ Parameter	**Proposed Device**	**Predicate Device**
510k	K180021	K973842
Intended Use/ Indications for Use	The device is indicated to aid in supporting and positioning adult and pediatric patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.
Design Features	The hand grips are optional accessories and are attached to the indexing on the side of the extensions and Couchtops. The Hand Grips provide a location for patients to place their hands, or to grasp, during treatments. The Hand Grips are ergonomically shaped, there is a defined left-Hand Grip and right-Hand Grip for patient positioning and comfort.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.
Principle of Operation	Mechanical devices without the use of software or electronics.	

Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).
Sterility	N/A Devices are non-sterile

MTIL662502	Patient Hand Grip	
Component/ Parameter	**Proposed Device**	**Predicate Device**
510k	K180021	K973842
Intended Use/ Indications for Use	The device is indicated to aid in supporting and positioning adult and pediatric patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.
Design Features	The hand grips are optional accessories and are attached to the indexing on the side of the extensions and Couchtops. The Hand Grips provide a location for patients to place their hands, or to grasp, during treatments. The Hand Grips are ergonomically shaped, there is a defined left-Hand Grip and right-Hand Grip for patient positioning and comfort.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.
Principle of Operation	Mechanical devices without the use of software or electronics.	
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).	
Sterility	N/A Devices are non-sterile	

MTVLG35FC	Vac-Lok Cushion			
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**	**Reference Device**
510k	K180021	K973842	K080072	K935300
Intended Use/ Indications for Use	The device is indicated to aid in supporting and positioning adult and pediatric patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and	Patient Positioning Devices are used to aid in the support and positioning of patients during an MRI.	The intended use of this device is to immobilize the patient during radiation therapy.

	used during image acquisition to support treatment planning.	other medical procedures.		
Design Features	The Vac-Lok™ Cushions indexes to the Couchtop for reproducible positioning of the patient from simulation to imaging to treatment. The Cushion is placed on a treatment table and formed around patient anatomy to allow for reproducible positioning. The Cushions are filled with polystyrene beads with a nylon casing which becomes rigid and forms to the patient's anatomy when the vacuum removes air from the cushion through a valve	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The Vac-Lok™ Cushions indexes to the Couchtop for reproducible positioning of the patient from simulation to imaging to treatment. The Cushion is placed on a treatment table and formed around patient anatomy to allow for reproducible positioning. The Cushions are filled with polystyrene beads with a nylon casing which becomes rigid and forms to the patient's anatomy when the vacuum removes air from the cushion through a valve	The Vac-Lok™ Cushions indexes to the Couchtop for reproducible positioning of the patient from simulation to imaging to treatment. The Cushion is placed on a treatment table and formed around patient anatomy to allow for reproducible positioning. The Cushions are filled with polystyrene beads with a nylon casing which becomes rigid and forms to the patient's anatomy when the vacuum removes air from the cushion through a valve
Principle of Operation	Mechanical devices without the use of software or electronics.			
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).			
Sterility	N/A Devices are non-sterile			

151004	Combifix Cushion		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K060737
Intended Use/ Indications for Use	The device is indicated to aid in supporting and positioning adult and pediatric patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Positioning of hip and lower extremities of a patient during radiotherapy and diagnostics.

	acquisition to support treatment planning.		
Design Features	The Combifix Cushion indexes to the Couchtop and combines the Kneefix and Feetfix for reproducible positioning of a patient. The Combifix Cushion provides patient support to the leg region and ease to the back region.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The Combifix Cushion indexes to the Couchtop and combines the Kneefix and Feetfix for reproducible positioning of a patient. The Combifix Cushion provides patient support to the leg region and ease to the back region.
Principle of Operation	Mechanical devices without the use of software or electronics.		
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).		
Sterility	N/A Devices are non-sterile		

Support Garments

CRTBRA01	Chabner XRT® Radiation Bra		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K121284
Intended Use/ Indications for Use	The device is indicated to aid in supporting adolescent and adult patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. The device is not intended for use with patients under 12 years of age.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Chabner XRT™ Garments are intended to be used as an aid in the support of the patient during X-ray, computed tomography, magnetic resonance imaging, radiotherapy, and other diagnostic radiological procedures. The Chabner XRT Garments are not intended for pediatric use.
Design Features	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single

	single patient use and discarded at the end of the treatment cycle.		patient use and discarded at the end of the treatment cycle.
Principle of Operation	Mechanical devices without the use of software or electronics.		
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).		
Sterility	N/A Devices are non-sterile		

CRTBRA02	Chabner XRT® Radiation Bra		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K121284
Intended Use/ Indications for Use	The device is indicated to aid in supporting adolescent and adult patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. The device is not intended for use with patients under 12 years of age.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Chabner XRT™ Garments are intended to be used as an aid in the support of the patient during X-ray, computed tomography, magnetic resonance imaging, radiotherapy, and other diagnostic radiological procedures. The Chabner XRT Garments are not intended for pediatric use.
Design Features	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.
Principle of Operation	Mechanical devices without the use of software or electronics.		
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).		
Sterility	N/A Devices are non-sterile		

CRTBRA03	Chabner XRT® Radiation Bra		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K121284
Intended Use/ Indications for Use	The device is indicated to aid in supporting adolescent and adult patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. The device is not intended for use with patients under 12 years of age.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Chabner XRT™ Garments are intended to be used as an aid in the support of the patient during X-ray, computed tomography, magnetic resonance imaging, radiotherapy, and other diagnostic radiological procedures. The Chabner XRT Garments are not intended for pediatric use.
Design Features	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.
Principle of Operation	Mechanical devices without the use of software or electronics.		
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).		
Sterility	N/A Devices are non-sterile		

CRTBRA04	Chabner XRT® Radiation Bra		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K121284
Intended Use/ Indications for Use	The device is indicated to aid in supporting adolescent and adult patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and	Chabner XRT™ Garments are intended to be used as an aid in the support of the patient during X-ray, computed tomography, magnetic resonance imaging, radiotherapy, and other

	used during image acquisition to support treatment planning. The device is not intended for use with patients under 12 years of age.	other medical procedures.	diagnostic radiological procedures. The Chabner XRT Garments are not intended for pediatric use.
Design Features	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.
Principle of Operation	Mechanical devices without the use of software or electronics.		
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).		
Sterility	N/A Devices are non-sterile		

CRTBRA05	Chabner XRT® Radiation Bra		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K121284
Intended Use/ Indications for Use	The device is indicated to aid in supporting adolescent and adult patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. The device is not intended for use with patients under 12 years of age.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Chabner XRT™ Garments are intended to be used as an aid in the support of the patient during X-ray, computed tomography, magnetic resonance imaging, radiotherapy, and other diagnostic radiological procedures. The Chabner XRT Garments are not intended for pediatric use.
Design Features	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return

	be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.	positioning and immobilization.	to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.
Principle of Operation	Mechanical devices without the use of software or electronics.		
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).		
Sterility	N/A Devices are non-sterile		

CRTBRA06	Chabner XRT® Radiation Bra		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K121284
Intended Use/ Indications for Use	The device is indicated to aid in supporting adolescent and adult patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. The device is not intended for use with patients under 12 years of age.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Chabner XRT™ Garments are intended to be used as an aid in the support of the patient during X-ray, computed tomography, magnetic resonance imaging, radiotherapy, and other diagnostic radiological procedures. The Chabner XRT Garments are not intended for pediatric use.
Design Features	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.
Principle of Operation	Mechanical devices without the use of software or electronics.		

Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).
Sterility	N/A Devices are non-sterile

CRTBRA07	Chabner XRT® Radiation Bra		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K121284
Intended Use/ Indications for Use	The device is indicated to aid in supporting adolescent and adult patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. The device is not intended for use with patients under 12 years of age.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Chabner XRT™ Garments are intended to be used as an aid in the support of the patient during X-ray, computed tomography, magnetic resonance imaging, radiotherapy, and other diagnostic radiological procedures. The Chabner XRT Garments are not intended for pediatric use.
Design Features	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.
Principle of Operation	Mechanical devices without the use of software or electronics.		
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).		
Sterility	N/A Devices are non-sterile		

CRTBRA08	Chabner XRT® Radiation Bra		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K121284

Intended Use/ Indications for Use	The device is indicated to aid in supporting adolescent and adult patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. The device is not intended for use with patients under 12 years of age.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Chabner XRT™ Garments are intended to be used as an aid in the support of the patient during X-ray, computed tomography, magnetic resonance imaging, radiotherapy, and other diagnostic radiological procedures. The Chabner XRT Garments are not intended for pediatric use.
Design Features	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.
Principle of Operation	Mechanical devices without the use of software or electronics.		
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).		
Sterility	N/A Devices are non-sterile		

CRTBRA09	Chabner XRT® Radiation Bra		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K121284
Intended Use/ Indications for Use	The device is indicated to aid in supporting adolescent and adult patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. The device is not intended for use with patients under 12 years of age.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Chabner XRT™ Garments are intended to be used as an aid in the support of the patient during X-ray, computed tomography, magnetic resonance imaging, radiotherapy, and other diagnostic radiological procedures. The Chabner XRT Garments are not intended for pediatric use.

Design Features	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.
Principle of Operation	Mechanical devices without the use of software or electronics.		
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).		
Sterility	N/A Devices are non-sterile		

CRTEXT01	Bra Extender		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K121284
Intended Use/ Indications for Use	The device is indicated to aid in supporting adolescent and adult patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning. The device is not intended for use with patients under 12 years of age.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	Chabner XRT™ Garments are intended to be used as an aid in the support of the patient during X-ray, computed tomography, magnetic resonance imaging, radiotherapy, and other diagnostic radiological procedures. The Chabner XRT Garments are not intended for pediatric use.
Design Features	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The device is composed of several pliable materials stitched together. A patient is measured and fit by the provider. The adjustable locations of the bra are able to be marked to return to the same position for each treatment. The bra is to be single patient use and discarded at the end of the treatment cycle.

	discarded at the end of the treatment cycle.		
Principle of Operation	Mechanical devices without the use of software or electronics.		
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).		
Sterility	N/A Devices are non-sterile		

Breast Positioning Devices

MTM400	C-Qual M with Monarch		
Component/ Parameter	**Proposed Device**	**Predicate Device**	**Reference Device**
510k	K180021	K973842	K974703
Intended Use/ Indications for 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. The device is also used during image acquisition to support treatment planning. The device is not intended for use with patients under 12 years of age.	The intended use of the MED-TEC, INC. Carbon Fiber Conformal Couch Top is to support and aid in positioning a patient during radiologic and other medical procedures.	The intended use of the MED-Tec, INC. Carbon Fiber Breast Board is to support and aid in positioning a patient during radiologic and other medical procedures.
Design Features	The Breastboard indexes to the Couchtop for reproducible positioning of a patient. The Breastboard provides patient support arms up positioning and allows for proper superior/inferior adjustments of the board to the patient's anatomy. The Breastboard elevates from 5 to 25 degrees with nine different tilt positions. The adjustable superior/inferior arms up and the variable elevation allows for reproducible immobilization and additional comfort while meeting clinically necessary positioning.	The Couch Top is placed onto the treatment pedestal and includes indexing for accessories to be attached onto to allow for patient positioning and immobilization.	The Breastboard indexes to the Couchtop for reproducible positioning of a patient. The Breastboard provides patient support arms up positioning and allows for proper superior/inferior adjustments and elevations of the board to the patient's anatomy. The adjustable superior/inferior arms up and the variable elevation allows for reproducible immobilization and additional comfort while meeting clinically necessary positioning.

Principle of Operation	Mechanical devices without the use of software or electronics.
Device Body Contact Category	Limited contact duration (<24 hours) for surface devices (skin).
Sterility	N/A Devices are non-sterile

G. Non-Clinical Testing and Literature Review

Non-Clinical testing was done to confirm the safety and effectiveness of the use of devices in the Proton environment and/or in path of Proton Beam. Devices were selected for performance testing based on whether they will be used in the path of the proton beam. Performance tests were completed to ensure these devices would not perturb or impact the proton beam in a way that cannot be accounted for in the proton treatment planning process. This data is provided as reference only, as it is standard practice that all hospitals and clinics perform their own respective treatment planning and attenuation testing due to variation in setup and machines.

Devices were evaluated, including edge effects, and were considered as safe and effective as the predicate. Because there is no recognized threshold for Proton attenuation, the criteria used for determining acceptable performance was to verify the part will not perturb or impact the proton beam in a way that cannot be accounted for in the facility's proton treatment planning process.

Devices that were not tested by CIVCO would not be used in the treatment zone or have the Proton Beam directed through the material. These devices are still safe to use in the Proton environment.

The risk analysis confirms the safety and effectiveness of similar devices used for pediatrics/adolescents, Proton Therapy and to ensure no new issues are raised.

Proton therapy is a widely accepted form of radiation therapy due to the characteristics of being minimally invasive, accuracy, and least harmful to surrounding healthy tissue. Couchtop, overlay, extension, thermoplastic mask, cushion, support garment, breastboard, and accessories are an integral part of patient simulation and external beam treatment delivery for proton and photon.

CIVCO devices are safe and effective for use in Proton Beam therapy as they immobilize/support/position the patient and can be transferred between modalities. Devices were evaluated, including edge effects, and were considered safe and effective for use in Proton. Because there is no recognized threshold for Proton attenuation, the criteria used for determining acceptable performance was to verify the part will not

perturb or impact the proton beam in a way that cannot be accounted for in the facility's proton treatment planning process.

Devices labeled for use in and MRI environment were previously cleared by predicate 510(k)'s included in this submission. Therefore, no additional MR testing is required.

The devices are intended for limited contact duration (<24 hours) for surface devices (skin). All devices are previously cleared and manufactured with the same or substantially equivalent material that was previously cleared and therefore no additional biocompatibility testing is required.

H. Conclusion

This premarket submission 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. The CIVCO devices were found to be safe and effective for use with adults, pediatrics, and/or adolescents in the Proton Therapy environment.