Sinmed head and shoulder positioning and immobilization systems. (Baseplates)

Date prepared 23-09-05
Submitter Sinmed BV
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Contact person: Caroline de Keijzer (Quality Manager)
Leo de Mooy (Technical Director)
Tradename: -Posifix 1,2,4,5,7 head and neck systems
-Positilt head inclination system
-Posifix Pediatric
-Headsupports
-Blocks and wedges
-Shouldersupport cushion
Common name: Head and shoulders immobilization systems.
Classification name: Linear medical accelerator
Classification: Class 2 devices, B92.5050 IYE
Intended use: Fixation and (re)positioning of the head- and neck during radiotherapy and diagnostics.

Substantial Equivalence Device: The Sinmed head and neck immobilization systems are defined as Substantially Equivalent (SE) to the Bionix 3-Way Head immobilizator; 3Way DeLuxe Reusable Frame, manufactured by Bionix Development corporation. Registration number: 1526854) and cleared by FDA with K933613

Description of the devices: See Sinmed product Catalogue 2006

Page: Product:
4 -Posifix 1,2,4,5,7 head and neck systems
8 -Positilt head inclination system
4 -Posifix Pediatric
9 -Headsupports
12 -Blocks and wedges
13 -Shouldersupport cushion

Summary of the technological characteristics of your device compared to the predicate device

The Sinmed devices indicated above are all designed to position the head- and neck of a patient for diagnostics and radiotherapy and exactly reposition it several times. All these products can be used in combination with each other to optimize the set-up of a patient. This is exactly the purpose of the Bionix 3-Way Head immobilizator. The same kind of construction and materials are used to reach this. Products from both companies are used for the same kind of radiotherapy treatments. These products from both companies are really competitive systems.
### 510(k) summary, IYE- positioning devices

<table>
<thead>
<tr>
<th><strong>Sinmed head and neck immobilization baseplates</strong></th>
<th><strong>Bionix 3-WAY HEAD IMMOBILIZER</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intended use</strong></td>
<td>Fixation and (re)positioning of the head- and neck area during radiotherapy and diagnostics.</td>
</tr>
<tr>
<td><strong>Target population</strong></td>
<td>Radiotherapy patients with tumors in head- and neck area.</td>
</tr>
<tr>
<td><strong>Position of the patient</strong></td>
<td>Lying on a couch in prone or supine position. Shoulders and head are positioned in a certain position using accessories for an optimized treatment.</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td>Carbon fiber and acrylic, polyethylene foam. The skin contact materials carbon fiber and acrylic are exactly the same as those used in the predicate device. The cytotoxicity test of the carbon fiber top layer we use is enclosed in Chapter 11. The PE-Foam material is commonly used in radiotherapy, the toxicity report is enclosed in Chapter 11.</td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
<td>Square shaped baseplate which follows the patients contours of head (Posifix -4, -5, -7, Posifix) or head and shoulders (Posifix-1 and -2 and -Pediatric).</td>
</tr>
<tr>
<td><strong>Design / Shape</strong></td>
<td>Flat baseplate on which the thermoplastic mask and various headsupports can be placed. Using the Posifix or other accessories, the baseplate can be inclined to change the position of the head.</td>
</tr>
<tr>
<td><strong>Possible adjustments</strong></td>
<td>Head can be lifted or inclined by using the blocks and wedges or the Posifix system.</td>
</tr>
<tr>
<td><strong>Couch fixation</strong></td>
<td>The Aluminium fixation rails connects the baseplate to the couch. The adjustable aluminium rails can be mounted on all of our baseplates. They allow the baseplate to be locked down in the desired position on the simulator or treatment couch. Depending on the type of couch, one can choose from several mounting brackets. The SecureFit bar connects the baseplate to the couch. Our SecureFit bar was designed to index our immobilization devices to the Exact™ Couch for increased accuracy.</td>
</tr>
<tr>
<td><strong>Accessories</strong></td>
<td>Foam headsupports, blocks and wedges, which can position the head for an optimized treatment. Foam Shouldersupport cushion for a better and more comfortable positioning of the patient. Thermoplastic mask-material which can be placed on the baseplate with plastic profiles. Headsupports designed for a dedicated treatment can be used on these baseplates. Foam blocks and wedges can be used for a better and more comfortable positioning of the patient. Thermoplastic mask-material which can be placed on the baseplate with plastic profiles.</td>
</tr>
<tr>
<td><strong>Compatibility with the environment and other devices</strong></td>
<td>Can be used on all brands of couches in diagnostic and radiotherapy environment. Can be used on an Exact™ couch in diagnostic and radiotherapy environment.</td>
</tr>
</tbody>
</table>

**Brief discussion of the nonclinical tests submitted**

The Sinmed described devices above are competitive devices to the device to which substantial equivalence is claimed. Both are designed and used for the same purpose. No comparative investigations are performed, but from clinical experience is known that both products function in the same way.
Sinmed head and shoulders immobilization systems. (Extensionplates)

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Leo de Mooy (Technical Director)
Tradename: Posifix-EXT systems
Shoulderretractor
Couchtop Cover
Common name: Head and shoulders immobilization systems
Classification name: Linear medical accelerator
Classification: Class 2 devices, 892.5050 IYE
Intended use: Fixation and (re)positioning of the head- and neck during radiotherapy and diagnostics.

Substantial Equivalence Device: The Sinmed head and neck immobilization systems are defined as Substantially Equivalent (SE) to the Bionix, Versaboard, Model 7040, manufactured by Bionix Development Corporation, Registration number: 1526854) and cleared by FDA with K030051

Description of the devices: See Sinmed product Catalogue 2006

Page: Product:
8 Posifix-EXT systems
35 Shoulderretractor
5 Couchtop Cover

Summary of the technological characteristics of your device compared to the predicate device

The Sinmed Posifix-EXT system, in combination with the Shoulderretractor and the Couchtopcover, can exactly be compared with the Bionix Versaboard. These products from both companies are intended to position the head- and neck of the patient outside the couch, to optimize the treatment possibilities. The Bionix baseplate is longer and also supports the back and buttocks of the patient. Sinmed has chosen to design a shorter version, and creates this total support by using the couchtop cover. On both systems the mask-material can be placed as well as a choice of headsupports for the positioning of the head. In order to further increase the space around the head of the patient, the shoulders should be suppressed. Sinmed uses a separate Shoulderretractor for this, and Bionix uses the relocatable shoulder suppression system which can be integrated in the baseplate. Both systems are placed and locked on the cranial side of the radiotherapy treatment couch. Both systems are specially developed for use during radiotherapy treatment, and not during diagnostics.
### 510(k) summary, IYE- positioning devices

<table>
<thead>
<tr>
<th>Sinmed head and neck immobilization baseplates (Extensionplate)</th>
<th>Bionix VERSABOARD, MODEL 7040</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intended use</strong></td>
<td>Fixation and (re)positioning of the head- and neck during radiotherapy, especially IMRT-treatment.</td>
</tr>
<tr>
<td>Target population</td>
<td>Patient with tumors in head- and neck-area, treated with IMRT-techniques.</td>
</tr>
<tr>
<td>Special feature in relation to head and shoulder immobil. systems (baseplates)</td>
<td>These extension plates position the head- and shoulders of the patient outside the couch, which enlarges the radiotherapy treatment possibilities.</td>
</tr>
<tr>
<td>Position of the patient</td>
<td>Shoulderretractor suppresses the shoulders for an optimized treatment.</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td>Carbon fiber sandwich construction, PE-foam.</td>
</tr>
<tr>
<td>Dimensions</td>
<td>Baseplate supports the head and shoulders of the patient. When also using the couchtop cover, the patient support is completely flat from head to buttocks.</td>
</tr>
<tr>
<td>Design/Shape</td>
<td>Head- and shoulders are supported by the baseplate and positioned outside the couch.</td>
</tr>
<tr>
<td>Possible adjustments</td>
<td>No adjustments possible with the baseplate. Adjustments in positioning of the head- and shoulders can be done by using accessories like different headsupports or the shoulderretractor.</td>
</tr>
<tr>
<td>Couchfixation</td>
<td>Flat baseplate which hooks onto the cranial side of the treatment couch and can be locked. After mounting onto the couch, the construction is fixed with a locking mechanism.</td>
</tr>
<tr>
<td>Accessories</td>
<td>- Thermoplastic mask-material which can be placed on the baseplate with fixation profiles. - Various headsupports designed for a dedicated treatment can be used on this baseplate. - Couchtop Cover to overcome the height difference when also using other baseplates.</td>
</tr>
<tr>
<td>Compatibility with the environment and other devices</td>
<td>Three types of which each can be placed on a Varian, Siemens or Elekta couch.</td>
</tr>
</tbody>
</table>

**Brief discussion of the nonclinical tests submitted**

The Sinmed described devices above are competitive devices to the device to which substantial equivalence is claimed. Both are designed and used for the same purpose. No comparative investigations are performed, but from clinical experience is known that both products function in the same way.
510(k) summary, IYE- positioning devices

Sinmed lung and thorax immobilization systems

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Phone: 0031-182-394495
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Contact person: Caroline de Keijzer (Quality Manager)
Leo de Mooy (Technical Director)
Tradename: -Thorawedge
-Posirest
-Posiboard
-PET-armsupport
Common name: Lung and thorax immobilization systems
Classification name: Linear medical accelerator
Classification: Class 2 devices, 892.5050 IYE
Intended use: Positioning the patient for irradiation in the lung- and thorax area.
Substantial Equivalence Device: The Sinmed Lung and thorax immobilization systems are defined as Substantially Equivalent (SE) to the MedTec CARBON FIBER BREAST BOARD, manufactured by MED-TEC INC. (Registration number: 1932738) and cleared by FDA with K974703.

Description of the devices: See Sinmed product Catalogue 2006

Summary of the technological characteristics of your device compared to the predicate device

The Medtec Breastboard is a device intended to position patients undergoing irradiation treatment in the breast- and lung area. This is exactly the same purpose of the Sinmed devices in this group.

The patient support of the Medtec Breastboard can be inclined for better treatment. This same inclination of the upper body is also possible with the Sinmed Posiboard and the Thorawedge.

To keep the arms out of the treatment area, arms above the head, various armsupports can be fixed on the Medtec Breastboard. This fixation of armsupports is also possible on the Sinmed Posiboard. This positioning of the arms above the head to achieve more space around the breast and lung-area is also the exact intended use of the Sinmed Posirest and PET-armsupport and the Thorawedge system.

The features of the Medtec Breastboard can all be found in the Sinmed Posiboard. The other three Sinmed lung and thorax immobilization systems are less complicated devices with the same purpose, each with its special features.
## 510(k) summary, IYE- positioning devices

**Sinmed Lung and thorax immobilization systems**

**MedTec Carbon Fiber Breast Board**

| Intended use | Positioning the patient for irradiation in the lung- and thorax area. |
| Target population | Patients with tumors in breast and thorax. |
| Position of the patient | Supine position, can be inclined, with arms positioned above the head. Carbon-fiber sandwich, there are no metal components in the vital scanning and treatment areas making it even more "CT-friendly". |
| Material | Carbon fiber sandwich construction, PE-Foam, and acrylic. Only non-metal materials are used, like foam, acrylic and carbon fiber sandwich in the treatment area. The skin contact material carbon fiber is exactly the same as that used in the predicate device. The cytotoxicity test of the carbon fiber top layer we use is enclosed in Chapter 11. The PE-Foam material is commonly used in radiotherapy, the toxicity report is enclosed in Chapter 11. The acrylic material is the same used in the Sinmed head and shoulder positioning and immobilization systems. (baseplates) and is identical to the material used in the predicate device Bionix 3-WAY HEAD IMMOBILIZER. |
| Dimensions | Optimized dimensions (width) to be CT-scanner compatible. Available in both standard and CT-compatible widths. |
| Design / Shape | Baseplate, with an aperture for placing various headsupports. Above the head the arms can be placed by using various armsupports. Baseplate, with an aperture for placing various headsupports. Above the head the arms can be placed by using various armsupports. |
| Possible adjustments | 0-25 degrees inclination possible with Posiboard and Thorawedge. 0 degrees inclination with Posirest and PET-armssupport. 0-25 degrees inclination possible. |
| Couchfixation | Posirest, Posiboard, PET-armssupport is fixed onto the couch with fixationstrips. The Medtec Carbon Fiber Breastboard is fixed onto the couch using the MedTec fixation rails. |
| Compatibility with the environment and other devices | Due to the chosen construction and materials, these products can be used during both diagnostics and radiotherapy. Due to the chosen construction and materials, these products can be used during both diagnostics and radiotherapy. |

### Brief discussion of the nonclinical tests submitted

The Sinmed described devices above are competitive devices to the device to which substantial equivalence is claimed. Both are designed and used for the same purpose. No comparative investigations are performed, but from clinical experience is known that both products function in the same way.
Sinmed pelvis and lower extremities immobilization systems (Bellyboard system)

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Phone: 0031-182-394495
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Leo de Mooy (Technical Director)
Tradename: Bellyboard
Prone thorax support cushion for Bellyboard
Common name: Pelvis and lower extremities immobilization systems (Bellyboard system)
Classification name: Linear medical accelerator
Classification: Class 2 devices, 892 5050 IYE
Intended use: The Sinmed Bellyboard has been developed in order to reduce the irradiated small bowel volume of gynaecological patients undergoing treatment in the pelvic region.

Substantial Equivalence Device: The Sinmed Pelvis and lower extremities immobilization systems (Bellyboard) are defined as Substantially Equivalent (SE) to the MedTec Bellyboard, manufactured by MedTec INC. (Registration number: 1932738) and cleared by FDA with K023293.

Description of the devices: See Sinmed product Catalogue 2006

Summary of the technological characteristics of your device compared to the predicate device

The Sinmed Bellyboard is substantially equivalent to the MedTec Advanced Bellyboard System in design, construction, and function. The Sinmed BellyBoard is flat and has a similar, generally rounded rectangular-shaped contour, with areas specifically designed for the head, abdomen, and thighs. The Prone Thorax support cushion has a contoured opening so that the patient may rest his/her head comfortably in the prone position during the treatment process. The abdominal cushion is also designed with an open, contoured cut out region. The patient is positioned over the abdominal cushion such that the belly drops into the cut out region during the radiation therapy session. The Sinmed BellyBoard is constructed in a manner similar to the Advanced Bellyboard System from Med-Tec, having a hollow thermoformed thermoplastic shell.
### 510(k) summary, IYE-positioning devices

<table>
<thead>
<tr>
<th>Sinmed Bellyboard system</th>
<th>MedTec Bellyboard</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intended use</strong></td>
<td>The Sinmed Bellyboard has been developed in order to reduce the irradiated small bowel volume of gynaecological patients undergoing treatment in the pelvic region.</td>
</tr>
<tr>
<td><strong>Target population</strong></td>
<td>Patients with tumors in the lower-abdomen area</td>
</tr>
<tr>
<td><strong>Position of the patient</strong></td>
<td>Prone position on this device</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td>Carbon fiber sandwich shell construction</td>
</tr>
<tr>
<td>The skin contact materials carbon fiber is exactly the same as that used in the earlier described predicate device: Bionix VERSABOARD, MODEL 7040. The cytotoxicity test of the carbon fiber top layer we use is enclosed in Chapter 11. PE-Foam: The PE-Foam material is commonly used in radiotherapy, the toxicity report is enclosed in Chapter 11.</td>
<td></td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
<td>Thick hollow construction with an aperture to place the belly. Flat top-part for positioning the arms and head.</td>
</tr>
<tr>
<td><strong>Design / Shape</strong></td>
<td>Ergonomic design for a comfortable position of the patient. Extra ruler for laser-alignment along the sides of the Bellyboard.</td>
</tr>
<tr>
<td><strong>Possible adjustments</strong></td>
<td>No adjustments possible, only by using additional cushions like the prone-cushion.</td>
</tr>
<tr>
<td><strong>Couchfixation</strong></td>
<td>Can be placed at indexed positions on the couch, using fixation strips.</td>
</tr>
<tr>
<td><strong>Accessories</strong></td>
<td>Prone cushion for Bellyboard to improve the position on the Bellyboard.</td>
</tr>
<tr>
<td><strong>Compatibility with the environment and other devices</strong></td>
<td>This device can be used both in combination with a CT-scanner and an accelerator.</td>
</tr>
</tbody>
</table>

**Brief discussion of the nonclinical tests submitted**

The Sinmed described devices above are competitive devices to the device to which substantial equivalence is claimed. Both are designed and used for the same purpose. No comparative investigations are performed, but from clinical experience is known that both products function in the same way.
510(k) summary, IYE- positioning devices

Sinmed Pelvis and lower extremities immobilization systems

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Contact person: Caroline de Keijzer (Quality Manager)
Leo de Mooy (Technical Director)

Tradename: -Posifix-12
-Multifix
-Combifix-system (Baseplate with Kneefix and Feetfix)
-Multi Purpose Support cushions

Common name: Pelvis and lower extremities immobilization systems

Classification name: Linear medical accelerator

Classification: Class 2 devices, 892.5050 IYE

Intended use: Positioning of hip and lower extremities of a patient for radiotherapy.

Substantial Equivalence Device: The Sinmed Pelvis and lower extremities immobilization systems depicted above are defined as Substantially Equivalent (SE) to the Hip Fixation System manufactured by MedTec, INC.
(Registration number: 1932738) and cleared by FDA with K950866.

Description of the devices: See Sinmed product Catalogue 2006

Page: Product:
35 Posifix-12
35 Multifix
35 Combifix-system (Baseplate with Kneefix and Feetfix)
53 Multi Purpose Support cushions

Summary of the technological characteristics of your device compared to the predicate device

All four products: Posifix-12, Multifix, Combifix-system (Baseplate with Kneefix and Feetfix) and the Multi Purpose Support cushions are products for positioning and immobilization of pelvis and lower extremities. These Sinmed products can be used individually or in combination with each other. The Posifix-12 and the Multifix are baseplates which should be used in combination with thermoplastic masks to fix the pelvis and lower extremities properly. The Medtec Hip Fixation system also uses the thermoplastic masks to fix the hips and extremities of the patient. The Sinmed Combifix is a system with which the pelvis and lower extremities are positioned in the same way as with the Medtec HipFix, but cannot be fixed with Posicast masks. The Sinmed Multi Purpose Support Cushions are actually important accessories of the Sinmed Multifix. With these cushions, the positioning of the extremities can be optimized and fixed with the thermoplastic mask-material.
### Sinmed Pelvis and lower extremities immobilization systems vs MedTec Hip Fixation System

<table>
<thead>
<tr>
<th>Intended use</th>
<th>Positioning of hip and lower extremities of a patient for radiotherapy.</th>
<th>The HipFix system is a popular choice for hip and pelvis immobilization in either the prone or supine position.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target population</td>
<td>Patients undergoing irradiation treatment in pelvis or lower extremities.</td>
<td>Patients undergoing irradiation treatment in pelvis or lower extremities.</td>
</tr>
<tr>
<td>Position of the patient</td>
<td>Supine position (Combifix) Or Prone and supine position. (Posifix-12, Multifix and MultiPurpose Support cushions)</td>
<td>Prone or supine position.</td>
</tr>
<tr>
<td>Material</td>
<td>Carbon fiber sandwich or plastic (acrylic and PE-Foam) devices. The skin contact materials carbon fiber is exactly the same as that used in the earlier described predicate device: Bionix VERSABOARD, MODEL 7040. The cytotoxicity test of the carbon fiber top layer we use is enclosed in Chapter 11. PE-Foam: The PE-Foam material is commonly used in radiotherapy, the toxicity report is enclosed in Chapter 11. The acrylic material is the same used in the Sinmed head and shoulder positioning and immobilization systems. (baseplates) and is identical to the material used in the predicate device Bionix 3-WAY HEAD IMMOBILIZER.</td>
<td>Carbon fiber with plastic</td>
</tr>
<tr>
<td>Design</td>
<td>Baseplate on which the hip and lower extremities of the patient can be positioned by using an individually shaped mask, or using a KneeFix- or Feetfix or a Multi Purpose Support Cushion.</td>
<td>Baseplate on which the hip and lower extremities of the patient can be positioned by using an individually shaped mask. Various cushions can be used to improve the patient positioning.</td>
</tr>
<tr>
<td>Possible adjustments</td>
<td>These devices can be adjusted to optimize the fit for the patient. Individual adjustment can be reached by changing distances or using Posicast masks.</td>
<td>These devices can be adjusted to optimize the fit for the patient. Individual adjustment can be reached by changing distances or using individual masks.</td>
</tr>
<tr>
<td>Couchfixation</td>
<td>Baseplates can be positioned on the couch or indexed positions.</td>
<td>Indexed Patient Positioning System-compatible</td>
</tr>
<tr>
<td>Accessories</td>
<td>Repovac vacuum cushions Thermoplastic Posicast mask material Multi Purpose Support Cushion.</td>
<td>Vac-Lok™ vacuum cushions Thermoplastic mask material</td>
</tr>
<tr>
<td>Compatibility with the environment and other devices</td>
<td>The -Posifix-12, Multifix, Combifix-system and Multi Purpose Support cushions can be used both in the diagnostic and treatment environment, due to the materials and construction chosen.</td>
<td>The Hip Fixation System can be used both in the diagnostic and treatment environment, due to the materials and construction chosen.</td>
</tr>
</tbody>
</table>

**Brief discussion of the nonclinical tests submitted**

The Sinmed described devices above are competitive devices to the device to which substantial equivalence is claimed. Both are designed and used for the same purpose. No comparative investigations are performed, but from clinical experience is known that both products function in the same way.
510(k) summary, IYE-positioning devices

Sinmed Repovac Cushions

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Phone: 0031-182-394495
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Tradename: Repovac cushions
Common name: Repovac cushions
Classification name: Linear medical accelerator
Classification: Class 2 devices, 892.5050 IYE

Intended use: Repovac vacuum cushions provide a comfortable, accurate and reproducible patient position throughout the total course of a radiation therapy treatment.

Substantial Equivalence Device:
The Sinmed Repovac cushions depicted above are defined as Substantially Equivalent (SE) to the Vac-Loc immobilization system manufactured by Med-Tec INC. (Registration number: 1932738) and cleared by FDA with K935300.

Description of the devices: See Sinmed product Catalogue 2006

Summary of the technological characteristics of your device compared to the predicate device:

Sinmed Repovac cushions, are plastic bags, filled with polystyrene beads and can be made vacuum to follow and keep the contour of a patient. This vacuum bag can be used during the total treatment to achieve an identical patient set-up every time. This is exactly the intended use and functioning of the MedTec vacuum cushions. Differences can be found in shape, color and top layer material.
## 510(k) summary, IYE- positioning devices

<table>
<thead>
<tr>
<th></th>
<th>Sinmed Repovac cushions</th>
<th>MedTec Vac-Lok immobilization System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intended use</strong></td>
<td>Repovac vacuum cushions provide a comfortable, accurate and reproducible patient position throughout the total course of a radiation therapy treatment.</td>
<td>When a complete vacuum is drawn through the quick-release valve, the cushion becomes a rigid and comfortable mold, offering accurate reproducibility throughout the course of simulation and treatment.</td>
</tr>
<tr>
<td><strong>Position of the patient</strong></td>
<td>The cushion forms a rigid mould of the patient by a vacuum that is drawn following the patient's contours. The quick-release valve and the airtight polyurethane bag allow the mould to maintain its shape over a long period of time. This ensures a reproducible patient set-up through imaging, simulation and treatment.</td>
<td>While semi-deflated, the cushion is easily molded around a patient’s anatomical contours. When a complete vacuum is drawn through the quick-release valve, the cushion becomes a rigid and comfortable mold, offering accurate reproducibility throughout the course of simulation and treatment.</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td>Polyurethane sheets with Polystyrene micropellets. The skin contact materials are exactly the same as those used in the predicate device.</td>
<td>A rugged clear urethane and an extra-durable nylon-reinforced blue urethane material that resists punctures. Rugged, radiotranslucent cushions are filled with tiny polystyrene beads.</td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
<td>Different dimensions available, square or a special shape for a special purpose.</td>
<td>Different dimensions available, square or a special shape for a special purpose.</td>
</tr>
<tr>
<td><strong>Design / Shape</strong></td>
<td>Various dimensions and shapes available for various purposes.</td>
<td>Various dimensions available, square or a special shape for a special purpose.</td>
</tr>
<tr>
<td><strong>Possible adjustments</strong></td>
<td>Cushion follows the individual contours of the patients.</td>
<td>Cushion follows the individual contours of the patients.</td>
</tr>
<tr>
<td><strong>Couchfixation</strong></td>
<td>Cushions cannot be fixed onto the couch.</td>
<td>Cushions cannot be fixed onto the couch.</td>
</tr>
<tr>
<td><strong>Accessories</strong></td>
<td>Vacuum pump, both manual and electrical “Moulding guides” to facilitate moulding of the cushion.</td>
<td>Electrical Vacuum pump “Helping hands” to facilitate moulding of the cushion.</td>
</tr>
<tr>
<td><strong>Compatibility with the environment and other devices</strong></td>
<td>Some Vacuum cushions are specially designed for use on Sinmed positioning devices to improve the positioning and comfort of the patient.</td>
<td>Some Vacuum cushions are specially designed for use on Medtec positioning devices to improve the comfort and positioning of the patient.</td>
</tr>
</tbody>
</table>

**Brief discussion of the nonclinical tests submitted**

The Sinmed described devices above are competitive devices to the device to which substantial equivalence is claimed. Both are designed and used for the same purpose. No comparative investigations are performed, but from clinical experience is known that both products function in the same way.
510(k) summary, IYE-positioning devices

Sinmed Posicast immobilization systems

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Contact person: Caroline de Keijzer (Quality Manager)
Leo de Mooy (Technical Director)
Trade name: Posicast
Common name: Posicast immobilization systems
Classification name: Linear medical accelerator
Classification: Class 2 devices, 892.5050 IYE

Intended use: Immobilization of a patient by using a thermoplastic mask.

Device: Substantially Equivalent (SE) to the Posicast Immobilization SYSTEM registered by Huestis Machine Corporation.
(Registration number: 1219183) and cleared by FDA with K926187. The following table compares the Sinmed POSICAST IMMOBILIZATION SYSTEM and the predicate device.

Huestis has registered this product when they were our representative in 1992. The distribution of Sinmed Posicast will be through another American company. Therefore we want to register this product under our own name. So the product we want to register is exactly the same as the material Huestis has registered in 1992.

Description of the devices: See Sinmed product Catalogue 2006

Summary of the technological characteristics of your device compared to the predicate device

<table>
<thead>
<tr>
<th>Sinmed POSICAST IMMOBILIZATION SYSTEM</th>
<th>Huestis Posicast Immobilization SYSTEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended use</td>
<td>Exactly the same</td>
</tr>
<tr>
<td>Target population.</td>
<td>&quot;</td>
</tr>
<tr>
<td>Position of the patient</td>
<td>&quot;</td>
</tr>
<tr>
<td>Material</td>
<td>&quot;</td>
</tr>
<tr>
<td>Dimensions</td>
<td>&quot;</td>
</tr>
<tr>
<td>Design / Shape</td>
<td>&quot;</td>
</tr>
<tr>
<td>Possible adjustments</td>
<td>&quot;</td>
</tr>
<tr>
<td>Couchfixation</td>
<td>&quot;</td>
</tr>
<tr>
<td>Accessories</td>
<td>&quot;</td>
</tr>
<tr>
<td>Compatibility with the environment</td>
<td>&quot;</td>
</tr>
<tr>
<td>and other devices</td>
<td>&quot;</td>
</tr>
</tbody>
</table>

Brief discussion of the nonclinical tests submitted
Both the Sinmed Posicast immobilization system and the Huestis Posicast immobilization SYSTEM are exactly the same. Therefore no clinical comparative tests are necessary.

Sinmed Premarket Notification Submission 510(k)
Dear Ms. Murphy:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

- 21 CFR 876.xxxx (Gastroenterology/Renal/Urology) 240-276-0115
- 21 CFR 884.xxxx (Obstetrics/Gynecology) 240-276-0115
- 21 CFR 892.xxxx (Radiology) 240-276-0120
- Other 240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

ManagE. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

Device Name:
1. Posifix 1.2.4.5.7 - head and neck systems
   -Posifix Pediatric
   -Headsupports
   -Blocks and wedges
   -Shoulder support cushion
2. Posifix-EXT systems
   -Shoulder retractor
   -Couchtop cover
3. Thorawedge
   -Posirest
   -Posi-board
   -PET- armsupport
4. Bellyboard
   -Prone thorax support cushion for Bellyboard
5. Posifix-12
   -Multifix
   -Combifix system (Baseplate with Kneefix and Feetfix)
   -Multi purpose support cushion
6. Repovac cushions
7. Posicast

Indications For Use:
1. Fixation and (re)positioning of the head- and neck area of the patient during radiotherapy and diagnostics.
2. Fixation and (re)positioning of the head- and neck area of the patient during radiotherapy and diagnostics.
5. Positioning of the hip and lower extremities of a patient during radiotherapy and diagnostics.
6. Fixation and (re)positioning of the patient during radiotherapy and diagnostics.
7. Fixation and (re)positioning of the patient during radiotherapy and diagnostics.

Prescription Use _X_ AND/OR Over-The-Counter Use _X_ (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)