NOV 2 0 2013

K132847
Page 1 of 8
iba



## 510(k) SUMMARY

## Ion Beam Applications S.A.

06 November 2013

## Submitter

Ion Beam Applications S.A.
Chemin du Cyclotron, 3
B-1348 Louvain-la-Neuve
Belgium
Contact person : Mr Baelen Michel
Phone : 32-10-47-58-45
Facsimile: 32-10-47-58-10
E-mail: Michel.Baelen@iba-group.com

## Contact and Agent for Ion Beam Applications S.A. in the US

Bruce D. Armon
Saul, Ewing, Remick & Saul
Centre Square West 38th Floor
Philadelphia, PA 19102-2186
Phone: (215) 972-7124
Facsimile: (215) 972-1906
E-mail: barmon@saul.com

iba

## Name of the Device

$I_2C$ (IBA Image Guided Therapy Consol) (brand name: adapt Insight)

## Classification Name

Medical charged-particle radiation therapy systems. (21 C.F.R. §892.5050)

## Predicate Devices

$I_2C$ is claimed to be equivalent to the predicate devices listed in table 1 below, based on the fact that they have the same intended use and principles of operation, and are substantially equivalent in terms of performance and technological characteristics.

**Table 1: List of the identified predicate devices and their indication for use**

| Device | Indication for use |
|---|---|
| **Verisuite (K080742, Medcom)** | The VeriSuite patient position verification system is used for verification and correction of the patient's position during a radiotherapy treatment with external beams or charged particles. It is based on stereoscopic X-ray images and DRRs calculated from a CT image series of the treatment region of the patient and information from the treatment planning. |
| **ExacTrac 3rd Party (K072046, Brainlab)** | The ExacTrac 3rd Party system is intended to be used in conjunction with the MHI-TM2000 radiation therapy linear accelerator system manufactured by Mitsubishi Heavy Industries, Ltd.<br>ExacTrac 3rd Party uses the images received from the MH1-TM2000 linear accelerator for analyzing the current patient position and calculating - when applicable - a necessary correction shift. The correction shift is then exported to the MHI-TM2000 linear accelerator.<br>The ExacTrac 3rd Party system uses stereoscopic x-ray or cone beam CT registration and optical tracking of infrared reflective markers in order to localize and correct the patient position before and during treatment. |
| **OBI (K040192 & K042720, Varian)** | The On-Board Imager device is used for verification of correct patient position in relation to isocenter and verification of the treatment fields in relation to anatomical and/or fiducial landmarks |

## Indication for Use of the device

$I_2C$ is used with a charged particle or photon radiation therapy system for localization of the patient position with respect to the therapy equipment and to provide correction feedback to the radiation therapy system.

iba

## Description of the device

For clinical use, $I_2C$ must be integrated into a radiation therapy system. $I_2C$ will interact with components of the radiation therapy center.

$I_2C$ supports the acquisition of 2D, 2D stereoscopic and 3D images using 2D detectors.

$I_2C$ will be used by the clinical therapist to verify by imaging that the treatment target position received from the treatment control applicative layer is 'valid', i.e. that it brings the center of the treatment target volume at the isocenter of the therapy equipment with required accuracy. If it is not, $I_2C$ will propose a correction shift – or correction vector – that will be exported to the radiation therapy system.

## Technological Characteristics of the device

### 1. Image acquisition

The $I_2C$ software supports the acquisition of 2D, 2D stereoscopic and 3D images using 2D detectors.

The 2D and 2D stereoscopic images can be acquired using one or multiple imaging devices arranged in various geometrical configurations.

The 3D images are created using a single 2D imaging device which rotates around the volume to be imaged. The 3D images are then reconstructed using the acquired 2D images and the associated spatial information (angle of acquisition).

The image acquisition supports a range of OEM devices[1], such as the following X-ray tubes, generators and detectors:

| | 2D | 2D/3D |
|---|---|---|
| **X-ray tube** | Varian B130H | Varian GS2075 |
| **Generator** | Sedecal SHF835 | Sedecal SHF845RF |
| **Detector** | Varian Paxscan 4030E | Thales Pixium RF4343 |

[1] *The conformity of these devices and their proper integration into the $I_2C$ system were ensured by the verification and validation activities followed during the development of the system and described in $I_2C$ VnV plan – MID 37685.*

## 2. Image registration

Image registration is used to verify, based on the reference and acquired images, that the position of the patient in regard to the equipment matches the treatment plan geometry and eventually compute a correction vector that can be applied to ensure correct patient positioning. It has been designed such that a sub-millimeter matching accuracy can be reached.

The registration provides a correction vector of up to 6 degrees of freedom that can be sent to third party systems.

### 2D image registration

The 2D or 2D stereoscopic image registration uses either:

- Intensity based information between the acquired X-ray planar images and the Digital Reconstructed Radiograph (DRR) (generated from the treatment planning reference CT) data or provided by Treatment Planning System – TPS -, ...), this is done automatically, or
- Markers that have been identified on the acquired X-ray planar images and the DRR generated from the CT data, or
- Manual registration of the images by drag and drop of one image to the other one.

### 3D image registration

The 3D image registration uses either

- Intensity based information between the acquired 3D data set and the CT data, or
- Manual registration of the images by drag and drop of one image to the other one.
- The registration provides a correction vector of 6 degrees of freedom that can be sent to third party system.

## 3. Connectivity to third party systems

The device exchanges data with 3rd party systems such as an Oncology Information System using either a push or a pull method, or any third party system supporting DICOM standards.

16a

## Comparison to the predicate devices

Like the predicate devices in Table 1, $I_2C$ is designed to be used with a charged particle or photon radiation therapy system for localization of the patient position with respect to the therapy equipment and to provide correction feedback to the radiation therapy device.

The predicate devices also provide the same or substantially equivalent functions, characteristics, and accessories.

Based on the purpose of the $I_2C$ system, its environment of use, its main components and features, the following elements have been used for comparison:

- Intended use
- Radiation type: clinical relevance, patient safety, known technology
- Acquisition geometry
- Detector type
- Image used as reference for matching
- Data compared during matching
- Type of matching approach
- Communication to 3rd party software

**Table 2: Comparison table of I2C with identified predicate devices**

| Characteristics | $I_2C$ | Verisuite (K080742, Medcom) | ExacTrac 3rd Party (K072046, Brainlab) | OBI (K040192 & K042720, Varian) |
|---|---|---|---|---|
| **Indication for use:** | | | | |
| • Verification of patient setup position | ✓ | ✓ | ✓ | ✓ |
| • Used with a charge particle radiation therapy system | ✓ | ✓ | | |
| • Used with a photon radiation therapy system | ✓ | ✓ | ✓ | ✓ |
| **Image acquisition:** | | | | |
| • High accuracy kV X-Ray imaging with digital flat panel | ✓ | ✓ | ✓ | ✓ |

iba

| Characteristics | $I_2C$ | Verisuite (K080742, Medcom) | ExacTrac 3rd Party (K072046, Brainlab) | OBI (K040192 & K042720, Varian) |
|---|---|---|---|---|
| • Stereoscopic acquisition | ✓ | ✓ | ✓ | ✓ |
| • Flexible X-Ray setup: various arrangements of panels, generators and tubes | ✓ | ✓ | | |
| **Image matching:** | | | | |
| • Registration using anatomical landmarks | ✓ | ✓ | ✓ | ✓ |
| • Registration using fiducial landmarks | ✓ | ✓ | ✓ | ✓ |
| • Registration using CBCT with planning CT | ✓ | | | ✓ |
| • Registration of radiographs with DRR generated from planning CT | ✓ | ✓ | ✓ | ✓ |
| o 2D/2D (5 DOF registration) | ✓ | ✓ | ✓ | ✓ |
| o 2D/3D (6 DOF registration) | ✓ | ✓ | ✓ | |
| **Interface to 3rd party applications:** | | | | |
| • Transfer of correction shift (correction vector) | ✓ | ✓ | ✓ | - |
| • DICOM exchange of clinical data | ✓ | ✓ | ✓ | ✓ |

Table 3 provides a comparison of $I_2C$ with predicate devices for some of characteristic specification.

**Table 3: Indication of performance and technological specification of $I_2C$ and its predicate devices**

| Performance / technological specification | $I_2C$ | Verisuite (K080742, Medcom) | ExacTrac 3rd Party (K072046, Brainlab) | OBI (K040192 & K042720, Varian) |
|---|---|---|---|---|

16a

| Performance / technological specification | $I_2C$ | Verisuite (K080742, Medcom) | ExacTrac 3rd Party (K072046, Brainlab) | OBI (K040192 & K042720, Varian) |
|---|---|---|---|---|
| Generator operating range (radiographic) | 40-150 kVp | 40-150 kVp | - | 40-150 kVp |
| Generator operating range (CBCT) | 40-125 kVp | N/A | N/A | 60-140 kVp |
| Flat panel pixel size | 148 µm | 127 µm | - | 194 µm |
| Flat panel pixel matrix | > 2880x2880 pixels | 3200x3200 pixels | - | 3200x2304 pixels |
| CBCT scale & distance accuracy | 1% | N/A | N/A | 1% |
| CBCT spatial resolution | At least 5 lp/cm | N/A | N/A | 4-7 lp/cm |
| CBCT low contrast resolution | 15mm@1% | N/A | N/A | 15mm@1% |
| CBCT numbers accuracy | +/- 40 HU | N/A | N/A | +/- 40 HU |
| CBCT Uniformity | +/- 40 HU | N/A | N/A | +/- 40 HU |
| Achievable matching accuracy | < 1 mm | < 1 mm | 1 - 2 mm | - |

Based on the previous analysis and discussion, we can state that for each of its functionalities regarding its intended use, I2C always has the same technological characteristics and is as safe and effective as at least one of the identified predicate devices. I2C performs as well or better as the identified predicate devices while not providing or using new functionality or technology.

**Nonclinical tests for determination of substantial equivalence**

When verifying the effectiveness and safety of the design and its implementation, part of the activities was done in a simulated clinical environment with the actual hardware and 3rd party software applications. The X-Ray imaging equipment was installed on a test bench in a vault appropriate for radiologic operation. The geometry of the system was adapted to represent different configuration setups. The rotation of the gantry was simulated by a rotation of the phantom on a turn table driven by a real gantry controller. A configuration of 3rd party software applications was setup in order to test the whole treatment workflow scenarios, including exception cases.

K132847
Page 8 of 8
iba



A second test environment was used to verify communication with different 3rd party software configurations (Elekta Mosaiq, Varian Aria) installed on their dedicated workstations.

Third, additional performance tests were done on a stand-alone system with appropriate datasets collected from simulated treatments and radiographs of phantom acquired in IBA treatment centres, from test bench data acquired with phantoms, and from anonymised patient data provided by IBA treatment centers.

As a fourth verification and validation strategy axis, a process of evaluation by a group of α-users has been put in place to assess the usability of the software. Throughout the development, intermediate releases are distributed to a group of reference users in proton therapy. A process has been put in place to collect a user evaluation of the system, especially regarding usability.

For a more elaborate description of the V&V activities, please refer to M-ID 37685 (I2C v1: V&V Plan).

## Conclusions

In conclusion, the verification and validation activities insure that the device is as safe, as effective, and performs as well as the legally marketed device identified in Table 1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ion Beam Applications S.A.
% Mr. Bruce D. Armon, Partner
Saul Ewing LLP
Center Square West
1500 Market Street, 38th Floor
PHILADELPHIA PA 19102

November 20, 2013

Re: K132847
Trade/Device Name: $I_2C$
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: September 9, 2013
Received: September 23, 2013

Dear Mr. Armon:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K132847

Device Name: I2C

Indications For Use:

Indications For Use: I2C is used with a charged particle or photon radiation therapy system for localization of the patient position with respect to the therapy equipment and to provide correction feedback to the radiation therapy device.

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

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of Center for Devices and Radiological Health (CDRH)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health



.510(k) ___K132847_____