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D017 04 074 01 FDA 510(k) - Summary - Delta4 Phantom+ MR.docx

Version	Comment	Author	Description
01	released	Thomas Matzen	First Version

1 APPLICANT

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2 DEVICE

Trade Name	Delta^4 Phantom+ MR
Common Name	Pre-treatment Verification System (for Quality Assurance)
Classification Name	Medical charged-particle radiation therapy system, §892.5050, Product code: IYE

3 PREDICATE DEVICE

Predicate Device	Delta^4
510(k) Premarket submission number	K151180

4 DESCRIPTION

The device consists out of matrices of semiconductors embedded in a phantom. These matrices are inserted into the radiation field of a medical linear accelerator. If radiation (from a radiotherapy treatment field) hits the semiconductors a signal is created and transferred to a computer where it is analysed and among others compared with the intended dose distribution.

The new device Delta^4 Phantom+ MR is equivalent in form and function to the cleared device Delta^4 Phantom+, but has been verified as an MR-conditional product.

5 COMPARISON WITH THE PREDICATE DEVICE

Area	Delta^4 Phantom+ (predicate device)	Delta^4 Phantom+ MR (new device)	Comparison
Intended Use	The intended use of the device is • quality assurance of patient specific treatment delivery prior to the treatment in IMRT (including VMAT) and 4DRT (e.g. respiratory gating and tumour tracking). • quality assurance of the radiation delivery system.	*Same as predicate device.*	Both the new and the predicate device have the same intended use.
Intended User	The intended user is a health care professional in the field of radiotherapy like a medical physicist or a dosimetrist who have been educated in the safe use of the device.	*Same as predicate device.*	Both the new and the predicate device have the same intended User.

5.1 Use context

5.1.1 Identical for both devices

The use context regarding

- patient contact (no patient contact)
- spatial use (professional healthcare environment)
- social use (users are only health care professionals who have been educated in the safe use of the device)
- Hygienic use (clean but not sterile)
- general physical use (controlled environmental conditions, no sharp accelerations)
- activity use (set up, power on, treatment plan delivery for QA purpose)

are identical for the new and the predicate device.

5.1.2 Differences

There are differences regarding physical use context regarding strong magnetic fields: The predicate device is MR unsafe and is never used in strong magnetic fields. The new device is MR conditional and can be used in strong magnetic fields (typically between 0.35T and 1.5T). The

new device uses non-ferromagnetic materials (like aluminium) instead of ferromagnetic material (as found in the predicate device).

5.2 Energy

5.2.1 Identical for both devices

- Neither the new nor the predicate device deliver energy to the patient.
- Both the new and the predicate device have the same software functionality regarding power supply operation:
  - The software recognizes if the device is powered on and displays information about the connected hardware.
  - If the connected device is powered OFF the software informs the user that there is no working hardware connected.

5.2.2 Differences

The predicate device can be battery powered OR powered via a power supply unit. The battery is not MR conditional. Therefore the battery powered option is NOT available for the new device. The new device is always powered via the power supply unit (the same unit as used by the predicate device). Moreover the power cable has been prolonged in the new device so that the power supply unit can be placed outside the strong magnetic field of the MR-linac, e.g. outside the treatment room.

For obvious reasons battery status is not available for the new device in the software.

5.3 Design, Dimensions, Material

5.3.1 Identical for both devices

The parameters regarding

- Measurement phantom shape and dimension (cylinder, 22cm x 40cm)
- Phantom length including electronics (about 71cm)
- Phantom weight (about 27 kg)
- Phantom material (PMMA or Plastic Water)
- Detector placement (two 2D arrays, perpendicular to each other)
- Default detector array orientation (sagittal/coronal)

are <u>identical</u> for the new and the predicate device.

5.3.2 Differences

The new device has an additional housing with some electronic parts, which in the predicate device are found within the same housing as the rest of the electronics. The additional housing in the new device contains components that work more satisfactorily when placed outside the strong magnetic field.

5.4 Performance, technology, communication

5.4.1 Identical for both devices

The following parameter are identical for both the new and the predicate device:

- operating principal (detectors creating a signal in the radiation field of a medical linear accelerator, signal is transferred to computer program where it is analysed)
- Detector technology (semiconductors)
- Measured quantity (Dose)
- Software analysis (comparing measured with calculated dose)
- Main analysis parameters (Dose difference, distance to agreement, gamma index)
- communication between PC and router (ethernet cable)

5.4.2 Differences

- The predicate device software supports the predicate device. The software of the new device supports in addition also the new device. The new device is treated in the same way as the predicate device in the software. All functionality available for the predicate hardware is now available for the new device, no software functionality had to been added. The use of the software in combination with the new hardware is as efficient and as safe as with the predicate hardware.
- Communication between measuring hardware and accesspoint/router: The predicate device uses Wi-Fi 802.11n communication. To allow a stable communication between hardware and PC in areas with strong magnetic fields the new device relies on standard ethernet cables instead.

5.5 Standards met

5.5.1 Identical for both devices

Both devices meet IEC 61010-1 and IEC 60601-1-2.

5.5.2 Differences

Additionally the device is conform to ASTM F2052. The predicate has not been designed to be MR conditional. Small modifications (like substituting ferromagnetic parts with non-magnetic parts) made it possible to create the new (MR conditional) device.

5.6 Biocompatibility

5.6.1 Identical for both devices

Neither of the devices is in contact with patient or body fluids.

5.7 Compatibility with the environment and other devices, safety (mechanical, chemical, physical, thermal, radiation)

5.7.1 Identical for both devices

Neither of the devices is an accessory to another medical device.

Both devices work according to their intended use without being connected to other medical devices.

5.7.2 Differences

The predicate device is MR unsafe. The new device is MR conditional. This has been achieved by substituting some ferromagnetic materials in the predicate device with non-ferromagnetic materials.

5.8 Sterility

5.8.1 Identical for both devices

Neither of the devices is intended to be sterile.

5.9 Performance: comparison with Predicate

Comparison tests have been performed with the predicate device in clinical and non-clinical situations.
Among others pre-treatment verification measurements of numerous treatment plans have been performed with both the new device and the predicate device. The results were compared with each other and it was determined that the results had very good correlation.

6 SUMMARY

The new device is equivalent, in most cases identical with the predicate devices regarding safety, design and performance.

Whereas the predicate device is MR unsafe the new device is MR conditional. This has been achieved by substituting the few existing ferromagnetic parts with non-magnetic parts (like aluminium). This change does in no way effect the safety, usability or effectiveness in a negative way.