002_04_01

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)*

K183606

Device Name
Delta4 Phantom+ MR

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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