DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K162629

Device Name
IQM Integral Quality Monitor

Indications for Use *(Describe)*

The IQM Integral Quality Monitor is a large-area ionization chamber intended to be used for quality assurance verification measurements and documentation of the treatment delivery accuracy (beam shape, position and dose) from medical linear accelerators used for intensity modulated radiation therapy.

The data acquired by IQM is used to compare and verify a treatment dose (delivered dose) to the expected dose and to compile treatment delivery radiation beam data over time as part of a quality assurance program.

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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