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)*
K181498

Device Name
X-ray Imaging System for the McLaren Proton Treatement System

Indications for Use *(Describe)*
The X-ray Imaging System is intended to be used as a patient setup and localization tool that is capable of processing orthogonal or CBCT images acquired at the start of the treatment. The images will be compared against Digitally Reconstructed Radiographs or CTs that were used to define the treatment plan. The comparison will generate position correction vectors if required and provide them to the McLaren Proton Treatment System for patient position corrections prior to treatment.

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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