Section 4 Indications for Use Statement

FORM FDA 3881

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)*

K183332

Device Name
Esophageal Brachytherapy Applicator

Indications for Use *(Describe)*
The Esophageal Brachytherapy Applicator is intended for use with commercially available afterloader during brachytherapy. The purpose of the device is for delivery of radioactive source to the esophagus. This device is sterile, disposable and single-use.

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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