

Indications for Use

510(k) Number (if known): K130549

Device Name: INTRABEAM® Surface Applicator used with INTRABEAM® System

Indications for Use:

The INTRABEAM® Surface Applicator is intended to supply a specified radiation dose during applications exclusively in combination with the INTRABEAM System.

- During intraoperative radiotherapy, on a surgically exposed surface or in a tumor bed.
- During treatment of tumors on the body surface.

The INTRABEAM® Surface Applicator is designed to deliver a flat radiation field directly at the applicator's surface.

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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