

## Indications for Use

510(k) Number (if known): K121653

Device Name: INTRABEAM® System with INTRABEAM® Spherical Applicators

### Indications for Use:

The INTRABEAM® System is indicated for radiation therapy treatments. The INTRABEAM® Spherical Applicators are indicated for use with the INTRABEAM® System to deliver a prescribed dose of radiation to the treatment margin or tumor bed during intracavity and intraoperative radiotherapy treatments.

The INTRABEAM® Spherical Applicators used with the INTRABEAM System are able to deliver a prescribed dose of intraoperative radiation in conjunction with whole breast irradiation, based upon the medical judgment of the physician. The safety and effectiveness of the INTRABEAM System as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

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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Page 1 of \_\_\_\_\_