

Indications for Use

510(k) Number (if known): K090584

Device Name: Carl Zeiss INTRABEAM® System

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 or intraoperative radiotherapy treatments. The INTRABEAM® Balloon Applicator together with the INTRABEAM® System is intended to deliver intracavitary or interstitial radiation to the surgical margins following lumpectomy for breast cancer.

The safety and effectiveness of the INTRABEAM® System as a replacement for whole breast irradiation in the treatment of breast cancer has not yet been established.

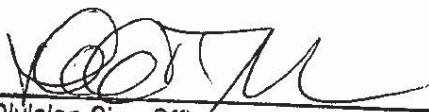
Prescription Use X
(Part 21 CFR 801 Subpart D)

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 Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
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