

510(k) Number (if known): K051055

Device Name: Carl Zeiss Surgical GmbH 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.

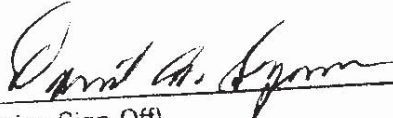
Prescription Use X
(Part 21 CFR 801 Subpart D)

~~AND/OR~~

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

(PLEASE DO NOT WRITE BELOW THIS LINE — CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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