

**K090584 INTRABEAM SYSTEM WITH BALLOON APPLICATOR
AND CBG SETS**Nov 24, 2009
266 days to decisionK090584 · Product code: **JAD** · Radiology
Source: <https://www.510kdatabase.net/k090584/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Therapeutic, X-ray (JAD)
Date received	Mar 3, 2009
Decision date	Nov 24, 2009
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Carl Zeiss Surgical GmbH
Location	North Attleboro, MA, US
Contact	MARK W SHEEHAN
510(k) history	4 submissions · 4 cleared · 2005-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090584/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026