FDA 510(k) Premarket Notification

K241174 INTRABEAM (700)

CLEARED

Jan 10, 2025
259 days to decision

K241174 · Product code: **JAD** · Radiology
Source: https://www.510kdatabase.net/k241174/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Therapeutic, X-ray (JAD)
Date received	Apr 26, 2024
Decision date	Jan 10, 2025
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	And accessories (INTRABEAM SMART Stand, INTRABEAM SMART Spherical Applicator, INTRABEAM Spherical Sizer Set, INTRABEAM Needle Applicator)

APPLICANT

Company	**Carl Zeiss Meditec, AG**
Location	Dublin, CA, US
Contact	Anke Seitz
Website	http://www.zeiss.com/meditec-ag/en_de/home.html
510(k) history	45 submissions · 44 cleared · 2004-2025

Carl Zeiss Meditec, AG is a global medical device manufacturer specializing in innovative solutions for ophthalmology and microsurgery. The company operates with a manufacturing facility in Dublin, US, and delivers diagnostic and surgical instruments to healthcare professionals worldwide. The company has received FDA 510(k) clearances from total submissions since 2004. Ophthalmic devices represent the dominant category, accounting for 71% of submissions. The latest clearance in 2025 reflects continued regulatory activity and product innovation in this specialized field. C...

REGULATORY CONSULTANT

Consulting firm	**Carl Zeiss Meditec, Inc.**
Contact	Chaitali Gawde

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov