FDA 510(k) Premarket Notification

K082264 CONTURA LUMEN MARKER

CLEARED

Sep 12, 2008
32 days to decision

K082264 · Product code: **JAQ** · Radiology
Source: https://www.510kdatabase.net/k082264/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	System, Applicator, Radionuclide, Remote-controlled (JAQ)
Date received	Aug 11, 2008
Decision date	Sep 12, 2008
Days to decision	32 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Senorx, Inc.**
Location	Irvine, CA, US
Contact	EBEN GORDON
510(k) history	30 submissions · 26 cleared · 2000-2023