FDA 510(k) Premarket Notification

K082159 CIVASTRING PD-103

CLEARED

Sep 30, 2008
61 days to decision

K082159 · Product code: **KXK** · Radiology
Source: https://www.510kdatabase.net/k082159/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	Jul 31, 2008
Decision date	Sep 30, 2008
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Civatech Oncology, Inc.**
Location	Mebane, NC, US
Contact	LOIS V SMART
510(k) history	3 submissions · 3 cleared · 2008-2019