FDA 510(k) Premarket Notification

K100793 UROSTATION 3D PROSTATE SUITE

CLEARED

Sep 22, 2010
184 days to decision

K100793 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k100793/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 22, 2010
Decision date	Sep 22, 2010
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Koelis**
Location	La Tronche, FR
Contact	CECILE DESMULIE
510(k) history	7 submissions · 7 cleared · 2010-2018