FDA 510(k) Premarket Notification

K222070 EndoNaut

CLEARED

Oct 25, 2022
103 days to decision

K222070 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k222070/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jul 14, 2022
Decision date	Oct 25, 2022
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Therenva Sas**
Location	Rennes, FR
Contact	Audrey Gallois
510(k) history	5 submissions · 5 cleared · 2014-2022