

**K212383 EndoNaut**Aug 31, 2021  
29 days to decisionK212383 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k212383/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Aug 2, 2021
Decision date	Aug 31, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212383/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026