

K222070 EndoNautOct 25, 2022
103 days to decisionK222070 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222070/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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