

K192182 C015Jan 17, 2020
158 days to decisionK192182 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k192182/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Aug 12, 2019
Decision date	Jan 17, 2020
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Micronica Srl
Location	Mirandola, IT
Contact	Massimo Tomasi
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	THEMA S.r.l.
Contact	Marisa Testa

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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