

K182086 ARCO FPAug 20, 2019
383 days to decisionK182086 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k182086/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Aug 2, 2018
Decision date	Aug 20, 2019
Days to decision	383 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	A.T.S. Applicazione Tecnologie Speciali S.R.L.
Location	Torre De? Roveri, IT
Contact	Duilio Finazzi
510(k) history	4 submissions · 4 cleared · 2019-2025

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