

K180601 Rotograph Prime 3D (under Trade mark Villa Sistemi Medicali), I-MAX 3D (under Trade mark Owandy Radiology)Nov 2, 2018
240 days to decisionK180601 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k180601/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Mar 7, 2018
Decision date	Nov 2, 2018
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Villa Sistemi Medicali S.P.A.
Location	Franklin Park, IL, US
Contact	Paolo Casagrande Santin
510(k) history	13 submissions · 13 cleared · 1999-2018

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