

K162190 Rotograph Prime (under trade mark Villa Sistemi Medicali), I-MAX (under trade mark Owandy Radiology)Jul 6, 2017
336 days to decisionK162190 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k162190/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Aug 4, 2016
Decision date	Jul 6, 2017
Days to decision	336 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162190/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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