

K182198 Panoura X-ERA PF/NF/MFJan 31, 2019
170 days to decisionK182198 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k182198/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Aug 14, 2018
Decision date	Jan 31, 2019
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	The Yoshida Dental Mfg. Co., Ltd.
Location	Tokyo, JP
Contact	Hidenori Watanabe
510(k) history	9 submissions · 9 cleared · 1982-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182198/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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