FDA 510(k) Premarket Notification

K223780 Lumos 3DX

CLEARED

Jul 6, 2023
202 days to decision

K223780 · Product code: **EHD** · Radiology
Source: https://www.510kdatabase.net/k223780/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Dec 16, 2022
Decision date	Jul 6, 2023
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**3Dio**
Location	Orem, UT, US
Contact	Douglas Hansen
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k223780/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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