FDA 510(k) Premarket Notification

K241393 ODI-Tech

CLEARED

Aug 30, 2024
106 days to decision

K241393 · Product code: **MUD** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k241393/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	May 16, 2024
Decision date	Aug 30, 2024
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Odi Medical AS**
Location	Oslo, NO
Contact	Wenche Groennvold
510(k) history	1 submissions · 1 cleared · 2024-2024