FDA 510(k) Premarket Notification

K223020 VS3-Iridium System (VS3-IR)

CLEARED

Oct 28, 2022
29 days to decision

K223020 · Product code: **OWN** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k223020/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Confocal Optical Imaging (OWN)
Date received	Sep 29, 2022
Decision date	Oct 28, 2022
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Visionsense, Ltd.**
Location	Washington, DC, US
Contact	Guy Wroclawski
510(k) history	13 submissions · 13 cleared · 2008-2022