FDA 510(k) Premarket Notification

K201988 T-Lite

CLEARED

Oct 30, 2020
105 days to decision

K201988 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k201988/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 17, 2020
Decision date	Oct 30, 2020
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sonoscanner**
Location	Ivry Sur Seine, FR
Contact	Bruno Richard
510(k) history	2 submissions · 2 cleared · 2017-2020

REGULATORY CONSULTANT

Consulting firm	**Smith Assoicates**
Contact	E.J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov