

K201988 T-LiteOct 30, 2020
105 days to decisionK201988 · 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 Associates
Contact	E.J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201988/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 15, 2026