

K193510 Terason uSmart3200T Ultrasound SystemJan 28, 2020
41 days to decisionK193510 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k193510/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 18, 2019
Decision date	Jan 28, 2020
Days to decision	41 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Teratech Corporation
Location	Burlington, MA, US
Contact	Steven R. Broadstone
510(k) history	2 submissions · 2 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Mark Job

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

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