

K201633 Terason uSmart 3200T Plus Ultrasound SystemJul 2, 2020
16 days to decisionK201633 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k201633/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 16, 2020
Decision date	Jul 2, 2020
Days to decision	16 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Teratech Corporation
Location	Burlington, MA, US
Contact	Benjamin Chiampa
510(k) history	2 submissions · 2 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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