

K201012 EPIQ Diagnostic Ultrasound System Series, Affiniti Diagnostic Ultrasound System Series, CX50 Diagnostic Ultrasound System, Sparq Diagnostic Ultrasound System, Lumify Diagnostic Ultrasound System

May 1, 2020
14 days to decision

K201012 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k201012/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Apr 17, 2020 |
| Decision date | May 1, 2020 |
| Days to decision | 14 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Philips Ultrasound, Inc. |
| Location | Santa Ana, CA, US |
| Contact | Deep Pal |
| 510(k) history | 46 submissions · 46 cleared · 1985-2021 |
