FDA 510(k) Premarket Notification

# K200603 AAA Model

**CLEARED**

Sep 20, 2020
195 days to decision

K200603 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k200603/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Mar 9, 2020 |
| Decision date | Sep 20, 2020 |
| Days to decision | 195 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 | Hebe Sun |
| 510(k) history | 46 submissions · 46 cleared · 1985-2021 |