FDA 510(k) Premarket Notification

# K092159 ACCUVIX V20 DIAGNOSTIC ULTRASOUND SYSTEM

**CLEARED**

Jul 28, 2009
12 days to decision

K092159 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k092159/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Jul 16, 2009 |
| Decision date | Jul 28, 2009 |
| Days to decision | 12 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Medison Co., Ltd.** |
| Location | Media, PA, US |
| Contact | SHIM KYUNG-AM |
| Website | http://www.medison.com/ |
| 510(k) history | 24 submissions · 24 cleared · 1990-2011 |