FDA 510(k) Premarket Notification

# K180621 EchoMark, EchoMark LP

**CLEARED**

Jun 6, 2018
89 days to decision

K180621 · Product code: **NEU** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k180621/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Marker, Radiographic, Implantable (NEU) |
| Date received | Mar 9, 2018 |
| Decision date | Jun 6, 2018 |
| Days to decision | 89 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Sonavex, Inc.** |
| Location | Baltimore, MD, US |
| Contact | David Narrow |
| 510(k) history | 3 submissions · 3 cleared · 2018-2025 |