FDA 510(k) Premarket Notification

# K162608 ClariFix Device

**CLEARED**

Feb 14, 2017
148 days to decision

K162608 · Product code: **GEH** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k162608/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Unit, Cryosurgical, Accessories (GEH) |
| Date received | Sep 19, 2016 |
| Decision date | Feb 14, 2017 |
| Days to decision | 148 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Arrinex, Inc.** |
| Location | Redwood City, CA, US |
| Contact | VAHID SAADAT |
| 510(k) history | 3 submissions · 3 cleared · 2016-2019 |