FDA 510(k) Premarket Notification

# K162721 Stimucel System, Stimucel Generator, Stimucel Treatment Wand, Stimucel Applicator

**CLEARED**

Dec 22, 2016
84 days to decision

K162721 · Product code: **NRB** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k162721/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Wound Cleaner, Ultrasound (NRB) |
| Date received | Sep 29, 2016 |
| Decision date | Dec 22, 2016 |
| Days to decision | 84 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Alliqua Biomedical, Inc.** |
| Location | Eden Prairie, MN, US |
| Contact | KATHY SIMPSON |
| 510(k) history | 2 submissions · 2 cleared · 2016-2017 |