FDA 510(k) Premarket Notification

# K050033 LUCION

**CLEARED**

Feb 11, 2005
35 days to decision

K050033 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k050033/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Jan 7, 2005 |
| Decision date | Feb 11, 2005 |
| Days to decision | 35 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Mevisys Co., Ltd.** |
| Location | Denton, TX, US |
| Contact | RICHARD LANZILLOTTO |
| 510(k) history | 2 submissions · 2 cleared · 2002-2005 |