FDA 510(k) Premarket Notification

# K141136 LEICA FL800

**CLEARED**

Aug 19, 2014
110 days to decision

K141136 · Product code: **IZI** · Radiology
Source: https://www.510kdatabase.net/k141136/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Angiographic (IZI) |
| Date received | May 1, 2014 |
| Decision date | Aug 19, 2014 |
| Days to decision | 110 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Leica Biosystems Richmond** |
| Location | Solon Mills, IL, US |
| Contact | BARBARA-ANN CONWAY-MYERS |
| 510(k) history | 1 submissions · 1 cleared · 2014-2014 |