FDA 510(k) Premarket Notification

# K121822 DELICOT

**CLEARED**

Sep 10, 2012
81 days to decision

K121822 · Product code: **HBA** · Neurology
Source: https://www.510kdatabase.net/k121822/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Neurosurgical Paddie (HBA) |
| Date received | Jun 21, 2012 |
| Decision date | Sep 10, 2012 |
| Days to decision | 81 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **American Surgical Company, LLC** |
| Location | Lynn, MA, US |
| Contact | ERIK PIASIO |
| 510(k) history | 2 submissions · 2 cleared · 2012-2013 |