FDA 510(k) Premarket Notification

# K092018 OMNIPRO INCLINE

**CLEARED**

Sep 18, 2009
74 days to decision

K092018 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k092018/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Accelerator, Linear, Medical (IYE) |
| Date received | Jul 6, 2009 |
| Decision date | Sep 18, 2009 |
| Days to decision | 74 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Iba Dosimetry GmbH** |
| Location | Bartlett, TN, US |
| Contact | CHUCK LINDLEY |
| 510(k) history | 3 submissions · 3 cleared · 2009-2020 |