FDA 510(k) Premarket Notification

# K092330 OC-SENSOR DIANA IFOB TEST

**CLEARED**

Jan 8, 2010
157 days to decision

K092330 · Product code: **OOX** · Hematology
Source: https://www.510kdatabase.net/k092330/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Automated Occult Blood Analyzer (OOX) |
| Date received | Aug 4, 2009 |
| Decision date | Jan 8, 2010 |
| Days to decision | 157 days |
| Third-party review | Yes |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Polymedco Cancer Diagnostics, LLC** |
| Location | Cortlandt Manor, NY, US |
| Contact | Candice Prowse |
| 510(k) history | 1 submissions · 1 cleared · 2010-2010 |