FDA 510(k) Premarket Notification

# K823359 OXYGEN CONSUMPTION MONITOR #OCM-0100

**CLEARED**

Jan 5, 1983
61 days to decision

K823359 · Product code: **DRY** · Cardiovascular
Source: https://www.510kdatabase.net/k823359/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY) |
| Date received | Nov 5, 1982 |
| Decision date | Jan 5, 1983 |
| Days to decision | 61 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Bentley Laboratories, Inc.** |
| Location | Mchenry, IL, US |
| Website | https://www.bentleyinstruments.com |
| 510(k) history | 55 submissions · 55 cleared · 1976-1993 |

Bentley Laboratories, Inc. is located in McHenry, US. The company has a historical record of FDA 510(k) device clearances spanning from 1976 to 1993. Bentley Laboratories received FDA 510(k) clearances from total submissions. The company specialized primarily in Cardiovascular devices, which represented approximately 80% of its regulatory submissions. Notable cleared devices included blood cardioplegia heat exchangers, venous reservoir bags, membrane oxygenators, and central venous catheters used in cardiac surgery and perfusion applications. The company is inactive and s...