

**K803231 THB 6000 HARDSHELL BUBBLE OXYGENATOR**Jan 16, 1981  
25 days to decisionK803231 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k803231/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Dec 22, 1980
Decision date	Jan 16, 1981
Days to decision	25 days
Third-party review	No

**APPLICANT**

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Company	<b>Travenol Laboratories, S.A.</b>
Location	McHenry, IL, US
Website	<a href="https://www.baxter.com">https://www.baxter.com</a>
510(k) history	206 submissions · 206 cleared · 1976-1988

Travenol Laboratories, S.A. is a medical device manufacturer based in McHenry, US. The company specializes in infusion, dialysis, and hospital care devices. Travenol Laboratories received FDA 510(k) clearances from total submissions between 1976 and 1988. The company's cleared devices span general hospital and gastroenterology/urology categories, including infusion systems, dialysis equipment, and administration sets. This regulatory record reflects the company's historical focus on critical care and renal therapy technologies. The company is inactive and represents a his...

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