

**K843640 XENON XE 127/XE 133 GAS DISPENSER**Jan 14, 1985  
119 days to decisionK843640 · Product code: IYT · Radiology  
Source: <https://www.510kdatabase.net/k843640/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Rebreathing, Radionuclide (IYT)
Date received	Sep 17, 1984
Decision date	Jan 14, 1985
Days to decision	119 days
Third-party review	No

**APPLICANT**

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Company	<b>Mallinckrodt Critical Care</b>
Location	Mchenry, IL, US
Contact	THOMAS W TUSING
Website	<a href="https://www.mallinckrodt.com">https://www.mallinckrodt.com</a>
510(k) history	92 submissions · 92 cleared · 1976-1989

Mallinckrodt Critical Care is a medical device manufacturer based in McHenry, US. Now part of Mallinckrodt plc following a 2025 merger and subsequent restructuring, the company maintains a significant historical regulatory record in critical care and specialty medical devices. The company received FDA 510(k) clearances from total submissions between 1976 and 1989. Device clearances span anesthesiology, cardiovascular, gastroenterology, and general hospital categories. Notable cleared products include tracheal tubes, temperature monitoring systems, catheters, and related c...

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Device record: <https://www.510kdatabase.net/k843640/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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