

**K780458 TRANSCUTANEOUS OXYGEN PERFUSION MONITOR**Oct 10, 1978  
201 days to decisionK780458 · Product code: **KLK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k780458/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Oxygen, Cutaneous, For Infant Not Under Gas Anesthesia (KLK)
Date received	Mar 23, 1978
Decision date	Oct 10, 1978
Days to decision	201 days
Third-party review	No

**APPLICANT**

---

Company	<b>Narco Air-Shields</b>
Location	Walker, MI, US
510(k) history	19 submissions · 18 cleared · 1978-1982

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k780458/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 22, 2026