

**K963481 ANODYNE CC**Aug 11, 1997  
342 days to decisionK963481 · Product code: **BSZ** · Anesthesiology  
Source: <https://www.510kdatabase.net/k963481/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gas-machine, Anesthesia (BSZ)
Date received	Sep 3, 1996
Decision date	Aug 11, 1997
Days to decision	342 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Heyer America, Inc.</b>
Location	Washington, DC, US
Contact	ED RANSOM
510(k) history	4 submissions · 4 cleared · 1991-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963481/> 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 25, 2026