

K092829 INSERTEASEDec 2, 2009
78 days to decisionK092829 · Product code: **OOW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k092829/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Applicator For Rectal Suppository (OOW)
Date received	Sep 15, 2009
Decision date	Dec 2, 2009
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Christcot Medical Company
Location	Sudbury, MA, US
Contact	JENNIFER D ENSIGN
510(k) history	1 submissions · 1 cleared · 2009-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092829/> Data sourced from FDA 510(k) public records (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. - Generated June 22, 2026