

K052858 SOOTHIES GEL PADSFeb 9, 2006
121 days to decisionK052858 · Product code: **NXH** · General Hospital
Source: <https://www.510kdatabase.net/k052858/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nursing Pad, Cohesive Gel (NXH)
Date received	Oct 11, 2005
Decision date	Feb 9, 2006
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Puronxy, Inc.
Location	San Diego, CA, US
Contact	LESLIE SEBASTAIN
510(k) history	1 submissions · 1 cleared · 2006-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052858/> 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 July 1, 2026