

**K032438 MODIFICATION TO: MONOJET PREFILL 0.9% SODIUM CHLORIDE FLUSH SYRINGE, MONOJET PREFILL HEPBRIN LOCK FLUSH SYRINGE**

Jun 30, 2004  
328 days to decision

K032438 · Product code: **NGT** · General Hospital  
Source: <https://www.510kdatabase.net/k032438/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saline, Vascular Access Flush (NGT)
Date received	Aug 7, 2003
Decision date	Jun 30, 2004
Days to decision	328 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Tyco Healthcare</b>
Location	Mansfield, MA, US
Contact	DAVID OLSON
510(k) history	14 submissions · 14 cleared · 2001-2007

---

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

Device record: <https://www.510kdatabase.net/k032438/> 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 June 26, 2026