

**K954729 PEN-INJECT 2.25**Jan 29, 1996  
108 days to decisionK954729 · Product code: **KZH** · General Hospital  
Source: <https://www.510kdatabase.net/k954729/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Syringe Needle (KZH)
Date received	Oct 13, 1995
Decision date	Jan 29, 1996
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Scandinavian Health , Ltd.</b>
Location	Washington, DC, US
Contact	THOMAS SCARLETT
510(k) history	1 submissions · 1 cleared · 1996-1996

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954729/> 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 July 6, 2026