

K124026 LOBSTER AUTO-INJECTORSep 13, 2013
259 days to decisionK124026 · Product code: **KZH** · General Hospital
Source: <https://www.510kdatabase.net/k124026/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Syringe Needle (KZH)
Date received	Dec 28, 2012
Decision date	Sep 13, 2013
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Scandinavian Health Limited
Location	Taoyuan City, TW
Contact	James Haynes
510(k) history	3 submissions · 3 cleared · 2012-2014

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