

K011544 HADGEL, 4 GRAM/SYRINGEAug 15, 2001
89 days to decisionK011544 · Product code: **LYA** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k011544/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Splint, Intranasal Septal (LYA)
Date received	May 18, 2001
Decision date	Aug 15, 2001
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Seikagaku Corp.
Location	Kitty Hawk, NC, US
Contact	JOHN J SHEA
510(k) history	1 submissions · 1 cleared · 2001-2001

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