

K043035 SEPRAGEL ENT BIORESORBABLE PACKING/STENTJul 11, 2005
250 days to decisionK043035 · Product code: **KHJ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k043035/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ent Synthetic-polyamide (mesh Or Foil Material) (KHJ)
Date received	Nov 3, 2004
Decision date	Jul 11, 2005
Days to decision	250 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genzyme Corporation
Location	Cambridge, MA, US
Contact	BARBARA PIZZA
510(k) history	6 submissions · 6 cleared · 2005-2010

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