

K970400 BONE SOURCE HYDROXYAPATITEMay 2, 1997
88 days to decisionK970400 · Product code: **LZK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k970400/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Malar (LZK)
Date received	Feb 3, 1997
Decision date	May 2, 1997
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Orthofix, Inc.
Location	Mckinney, TX, US
Contact	MARY BIGGERS
510(k) history	57 submissions · 57 cleared · 1996-2024

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