

K983457 OSTEOMARK NTX SERUM EIA

Feb 2, 1999
125 days to decision

K983457 · Product code: JMM · Chemistry
Source: <https://www.510kdatabase.net/k983457/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Column Chromatography & Color Development, Hydroxyproline (JMM)
Date received	Sep 30, 1998
Decision date	Feb 2, 1999
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ostex Intl., Inc.
Location	Seattle, WA, US
Contact	NANCY J.S. MALLINAK
510(k) history	5 submissions · 5 cleared · 1995-2001

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k983457/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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