

K955648 K-Y PERSONAL LUBRICANTJun 21, 1996
192 days to decisionK955648 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k955648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Dec 12, 1995
Decision date	Jun 21, 1996
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho Pharmaceutical Corp.
Location	Walker, MI, US
Contact	DIANE HERRON
510(k) history	9 submissions · 9 cleared · 1979-1996

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