

**K003278 COMPLETE HUMAN TUBAL FLUID (HTF) WITH SERUM  
SUBSTITUTE SUPPLEMENT, MODEL 9922**

Jan 17, 2001  
90 days to decision

K003278 · Product code: **MQL** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k003278/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Oct 19, 2000
Decision date	Jan 17, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Irvine Scientific Sales Co., Inc.</b>
Location	Santa Ana, CA, US
Contact	WENDELL LEE
510(k) history	40 submissions · 40 cleared · 1997-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k003278/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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