

**K100464 UTASWAKO I30 (INCLUDES ACCESSORIES),
UTASWAKO AFP-L3, CALIBRATOR SET, CONTROL L,
CONTROL H, SAMPLE DILUTION**Feb 23, 2011
370 days to decisionK100464 · Product code: **NSF** · Immunology
Source: <https://www.510kdatabase.net/k100464/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Alpha Fetoprotein L3 Subfraction (afp-I3%), For Hepatocellular Carcinoma Risk Assessment (NSF)
Date received	Feb 18, 2010
Decision date	Feb 23, 2011
Days to decision	370 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wako Chemicals USA, Inc.
Location	Mchenry, IL, US
Contact	MARTHA MURARI
510(k) history	124 submissions · 123 cleared · 1981-2011

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