

K083602 KAPPA LIGHT CHAINSSep 3, 2009
272 days to decisionK083602 · Product code: **DFH** · Immunology
Source: <https://www.510kdatabase.net/k083602/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Dec 5, 2008
Decision date	Sep 3, 2009
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	SENTINEL CH. SpA
Location	Milano, IT
Contact	YANGTSE PORTELLES
510(k) history	12 submissions · 12 cleared · 2007-2025

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