

K070810 ARCHITECT I THEOPHYLLINE REAGENTS AND CALIBRATORS (A-F)Jun 8, 2007
74 days to decisionK070810 · Product code: **LGS** · Toxicology
Source: <https://www.510kdatabase.net/k070810/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Theophylline (LGS)
Date received	Mar 26, 2007
Decision date	Jun 8, 2007
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biokit, S.A.
Location	Barcelona, ES
Contact	JOAN GUIXER
510(k) history	23 submissions · 23 cleared · 2005-2025

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