

K160447 Calprest NGNov 10, 2016
267 days to decisionK160447 · Product code: **NXO** · Immunology
Source: <https://www.510kdatabase.net/k160447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calprotectin, Fecal (NXO)
Date received	Feb 17, 2016
Decision date	Nov 10, 2016
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Eurospital S.P.A.
Location	Woodstock, GA, US
Contact	Claudia Brandolin
510(k) history	4 submissions · 4 cleared · 2014-2019

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