

K013148 BIOGENEX MONOCLONAL ANTI-ESTROGEN RECEPTOR(CLONE ER88)Feb 28, 2002
161 days to decisionK013148 · Product code: MYA · Pathology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunohistochemistry Antibody Assay, Estrogen Receptor (MYA)
Date received	Sep 20, 2001
Decision date	Feb 28, 2002
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biogenex Laboratories
Location	Mchenry, IL, US
Contact	GURVINDER S NANDA
510(k) history	12 submissions · 12 cleared · 1981-2002

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