

**K170028 FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor a, Clone EPI, RTU (Dako Onmis)**Dec 21, 2017  
352 days to decisionK170028 · Product code: MYA · Pathology  
Source: <https://www.510kdatabase.net/k170028/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunohistochemistry Antibody Assay, Estrogen Receptor (MYA)
Date received	Jan 3, 2017
Decision date	Dec 21, 2017
Days to decision	352 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dako Denmark A/S</b>
Location	Golstrup, DK
Contact	Lasse Post Moller
510(k) history	2 submissions · 2 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170028/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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