

**K153117 AESKUSLIDES ANA HEp-2-Gamma, HELIOS FULLY  
AUTOMATED IFA SYSTEM**Jul 28, 2016  
274 days to decisionK153117 · Product code: **DHN** · Immunology  
Source: <https://www.510kdatabase.net/k153117/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Oct 28, 2015
Decision date	Jul 28, 2016
Days to decision	274 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Aesku Systems GmbH&amp;Co.Kg</b>
Location	Wendelsheim, DE
Contact	TOM STECKLUM
510(k) history	1 submissions · 1 cleared · 2016-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153117/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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