

**K220595 NeoNavia Biopsy System**Sep 8, 2022  
191 days to decisionK220595 · Product code: **KNW** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k220595/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Mar 1, 2022
Decision date	Sep 8, 2022
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neodynamics AB</b>
Location	Lidingo, SE
Contact	Anna Forsberg
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Msquared Associates, Inc.</b>
Contact	LeAnn Latham

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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