

**K200318 UNIDRIVE S II ENT, DrillCut-X II-35 Shaver Handpiece,  
DrillCut-X II-35 N Shaver Handpiece**Oct 22, 2020  
258 days to decision

K200318 · Product code: ERL · Ear, Nose, Throat

Source: <https://www.510kdatabase.net/k200318/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Feb 7, 2020
Decision date	Oct 22, 2020
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>KARL STORZ Endoscopy-America, Inc.</b>
Location	Mchenry, IL, US
Contact	Alita McElroy
510(k) history	361 submissions · 361 cleared · 1980-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200318/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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