

**K143492 OSSEOSTAP Microdrill System (control unit and handpiece), OSSEOSTAP control unit (foot pedal), OSSEOSTAP handpiece**Mar 4, 2015  
86 days to decisionK143492 · Product code: ERL · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k143492/>**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	Dec 8, 2014
Decision date	Mar 4, 2015
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bien-Air Surgery SA</b>
Location	Le Noirmont, CH
Contact	Judith Clerc
510(k) history	5 submissions · 5 cleared · 2009-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143492/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026