

**K171037 PoreStar Patient Specific Implant**Dec 27, 2017  
265 days to decisionK171037 · Product code: **JOF** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k171037/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ent Synthetic, Porous Polyethylene (JOF)
Date received	Apr 6, 2017
Decision date	Dec 27, 2017
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Anatomics Pty, Ltd.</b>
Location	St Kilda, AU
Contact	Joanne Flatley
510(k) history	2 submissions · 2 cleared · 2017-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171037/> 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 June 20, 2026