

K182798 KIDScore D3Jul 19, 2019
290 days to decisionK182798 · Product code: **PBH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k182798/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Embryo Image Assessment System, Assisted Reproduction (PBH)
Date received	Oct 2, 2018
Decision date	Jul 19, 2019
Days to decision	290 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vitrolife A/S
Location	Viby J, DK
Contact	Belinda Dueholm
510(k) history	4 submissions · 4 cleared · 2015-2022

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