

K173075 ZyMot ICSI Sperm Separation Device, ZyMot Multi Sperm Separation Device (850µl, 3ml)Mar 8, 2018
160 days to decisionK173075 · Product code: **MQK** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k173075/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Sep 29, 2017
Decision date	Mar 8, 2018
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dxnow, Inc.
Location	Gaithersburg, MD, US
Contact	William T. Sharp
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173075/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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