

**K201162 Essence 55SP Large Monitor System**Aug 27, 2020  
119 days to decisionK201162 · Product code: **DXJ** · CardiovascularSource: <https://www.510kdatabase.net/k201162/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Cathode-ray Tube, Medical (DXJ)
Date received	Apr 30, 2020
Decision date	Aug 27, 2020
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenyang Torch-Bigtide Digital Technology Co., Ltd.</b>
Location	Shenyang, CN
Contact	Fu Ailing
510(k) history	2 submissions · 2 cleared · 2018-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201162/> 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 19, 2026