

**K201009 CHIRAVAC Blood Collection Needles**

Jul 21, 2021  
460 days to decision

K201009 · Product code: **JKA** · General Hospital  
Source: <https://www.510kdatabase.net/k201009/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA)
Date received	Apr 17, 2020
Decision date	Jul 21, 2021
Days to decision	460 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Chirana T. Injecta</b>
Location	Star? Tur?, SK
Contact	Zdenka Klbeckova
510(k) history	4 submissions · 4 cleared · 2021-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Empirical Testing Corp</b>
Contact	Nathan Wright

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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