

**K181248 Comarch e-Care Platform**Oct 22, 2018  
165 days to decisionK181248 · Product code: **DRG** · Cardiovascular  
Source: <https://www.510kdatabase.net/k181248/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	May 10, 2018
Decision date	Oct 22, 2018
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Comarch Healthcare SA</b>
Location	Krakow, PL
Contact	Irmina Serafin
510(k) history	1 submissions · 1 cleared · 2018-2018

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Mdi Consultants, Inc.</b>
Contact	Jigar Shah

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181248/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026