

**K914972 CARPENTIER-EDWARDS(R) FLEX ANNUL RING, 4500 TRICUS**Jan 9, 1992  
64 days to decisionK914972 · Product code: **KRH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k914972/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Ring, Annuloplasty (KRH)           |
| Date received         | Nov 6, 1991                        |
| Decision date         | Jan 9, 1992                        |
| Days to decision      | 64 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Baxter Healthcare Corp</b>             |
| Location       | Mchenry, IL, US                           |
| Contact        | Roberta Hines                             |
| 510(k) history | 505 submissions · 496 cleared · 1977-2019 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k914972/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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