

**K183094 CyclaPlex Correction System**Apr 26, 2019  
170 days to decisionK183094 · Product code: **HTN** · Orthopedic  
Source: <https://www.510kdatabase.net/k183094/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Washer, Bolt Nut (HTN)             |
| Date received         | Nov 7, 2018                        |
| Decision date         | Apr 26, 2019                       |
| Days to decision      | 170 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Cycla Orthopedics, Ltd.</b>        |
| Location       | Bat Shlomo, IL                        |
| Contact        | Rafi Herzog                           |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

**REGULATORY CONSULTANT**

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|-----------------|------------------------|
| Consulting firm | <b>Paladin Medical</b> |
| Contact         | Elaine Duncan          |

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

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