

K191537 eCarbon IBDsSep 26, 2019
108 days to decisionK191537 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k191537/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Cervical (ODP) |
| Date received | Jun 10, 2019 |
| Decision date | Sep 26, 2019 |
| Days to decision | 108 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Back 2 Basics Direct, LLC |
| Location | Independence, OH, US |
| Contact | Scot Miller |
| 510(k) history | 4 submissions · 4 cleared · 2015-2020 |

REGULATORY CONSULTANT

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|-----------------|-----------------------------|
| Consulting firm | Backroads Consulting |
| Contact | Karen E. Warden |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191537/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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