

FDA Mapper

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Market (US)

2015 Healthcare expenditure: \$3.2 Trillion

2015 Medical devices expenditure: \$140 Billion

Regulatory burden is a major risk for
manufacturers

Current state: PDFs

K043561

DEC 29 2004

VERTE-STACK™ Spinal System 510(k) Summary December 2004

I. Company: Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: Richard W.
Sr. Vice President

II. Proprietary Trade Name: VERTE-STACK™

III. Classification Name: Spinal
888.3060)

III. Product Description

The VERTE-STACK™ device is a minimally invasive body replacement to aid in the construction of a spine. The device is not intended to be a permanent device. The device is fabricated and manufactured from POLYMER. The device includes a tantalum marker.

The design of the VERTE-STACK™ device is of different sizes and heights. The stackable components are designed to suit the individual patient anatomy.

V. Substantial Equivalence

Documentation was provided which demonstrated the VERTE-STACK™ Spinal System to be substantially equivalent to the previously cleared VERTE-STACK™ Spinal System components found in K041556 and K040422.



“I would buy this.”

- **Matthew Alves** (former VP of business strategy at Stryker)

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Speeds up 510(k) exploration stage

Pre-market: Better match to similar devices
(stronger case, reduced risk, faster approval)

Post-market: Better tracking of recalls affecting
multiple generations

Use cases:

- Bringing new device to market
 - Largest unknown is the regulatory approval process
 - Lowering risk and improving efficiency in the product development cycle
- Dealing with product recalls and compliance
 - Determine recalled predicate devices that may be upstream from your device

Market Research Sources

http://www.trade.gov/topmarkets/pdf/Medical_Devices_Executive_Summary.pdf.

https://www.advamed.org/sites/default/files/resource/994_100515_guy_king_report_2015_final.pdf

[http://www.ey.com/Publication/vwLUAssets/ey-pulse-of-the-industry-2016/\\$FILE/ey-pulse-of-the-industry-2016.pdf](http://www.ey.com/Publication/vwLUAssets/ey-pulse-of-the-industry-2016/$FILE/ey-pulse-of-the-industry-2016.pdf)