FDA Mapper

Denis Foo Kune, Haitham Maya, Henry Marshall, Tom Kidd, Michael Kovalcik

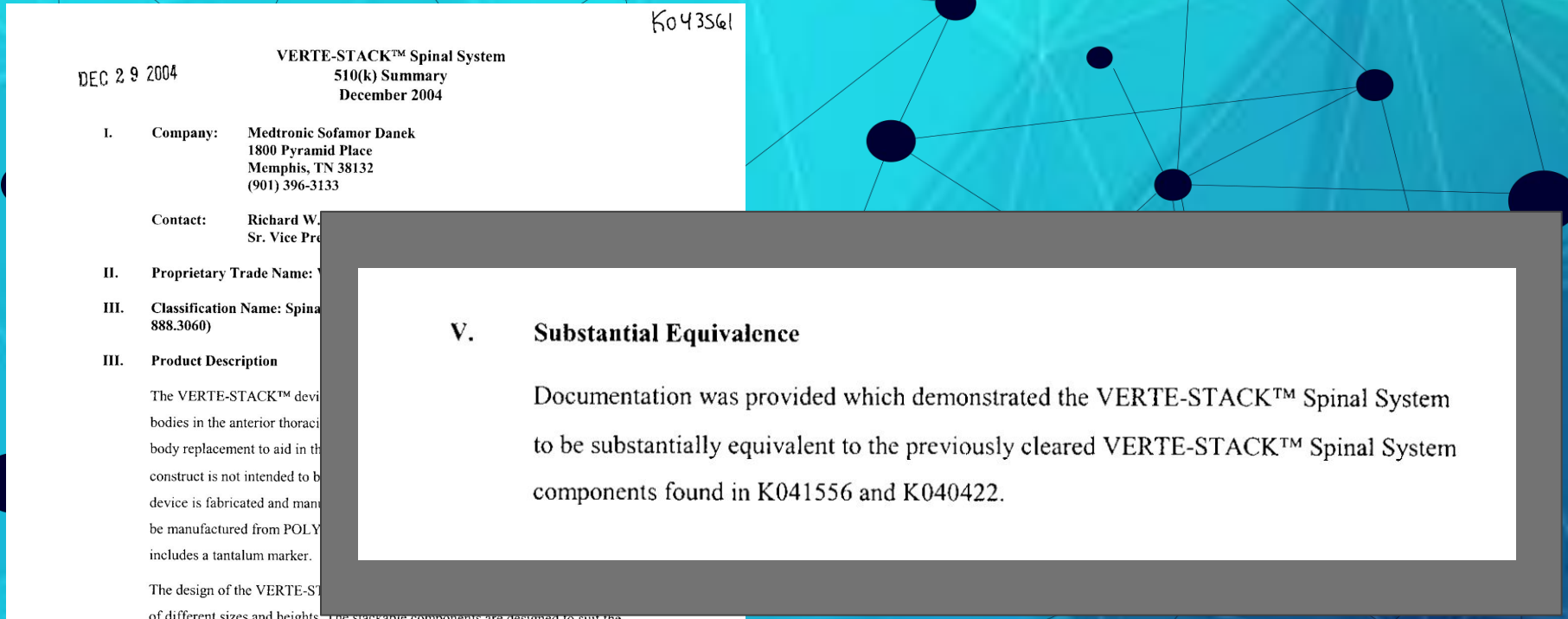
Market (US)

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 2 9 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 Pr

II. Proprietary Trade Name:

III. Classification Name: Spina
888.3060)

III. Product Description

The VERTE-STACK™ devi
bodies in the anterior thoraci
body replacement to aid in th
construct is not intended to b
device is fabricated and mani
be manufactured from POLY
includes a tantalum marker.

The design of the VERTE-S
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)

FDA Mapper

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:

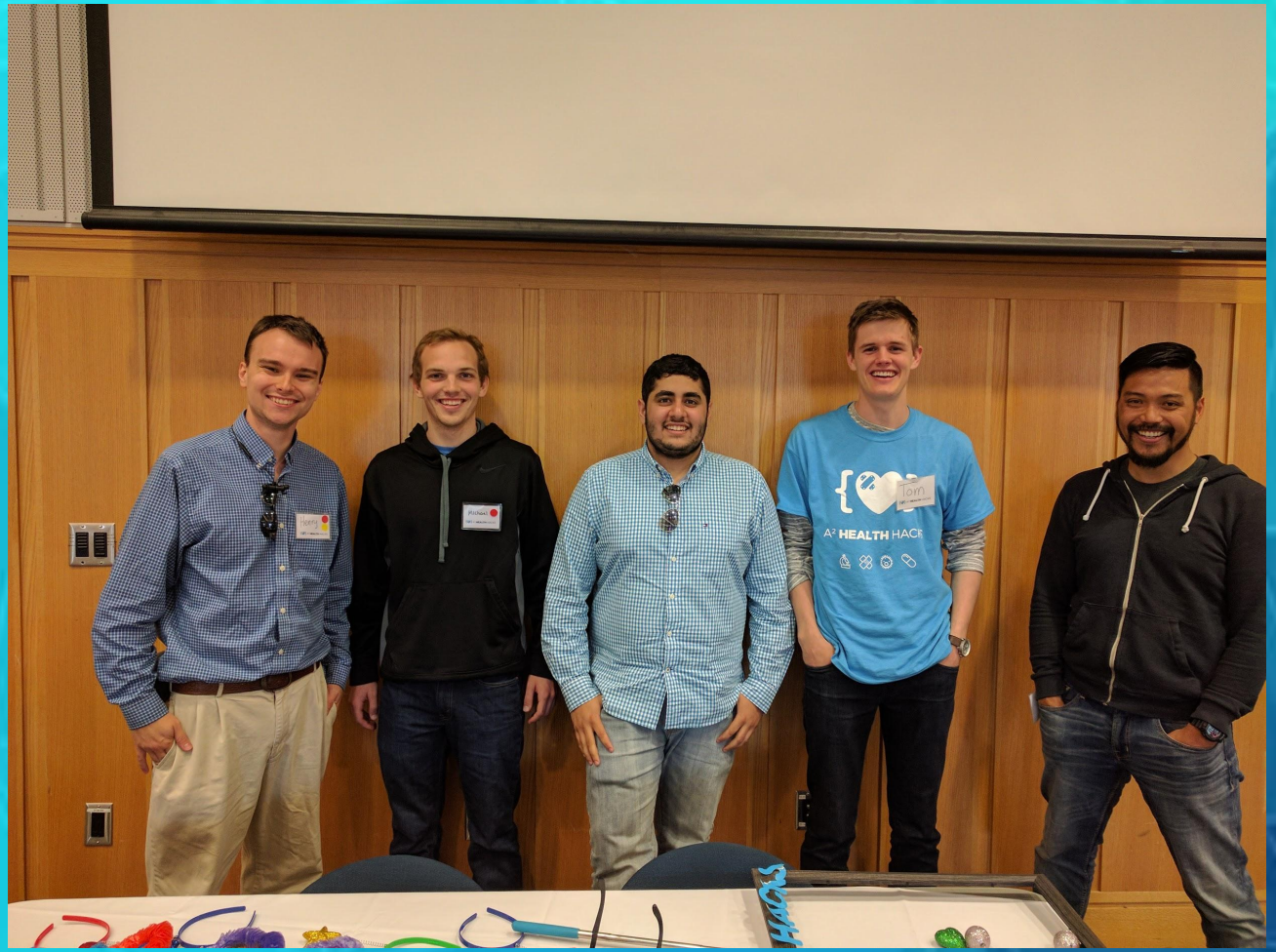
- Bringing new device to market
  - Largest unknown is the regulatory approval process
  - Lowering risk and improving efficiency in the product development cycle
- Dealing with product recalls and compliance
  - Determine recalled predicate devices that may be upstream from your device

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


A² HEALTH HACK