FDA Presentation: TOPAS™ System for Fecal Incontinence P140006

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Office of Device Evaluation
Center for Devices and Radiological Health

GU Advisory Panel Meeting
February 25, 2016

FDA Review Team

Function	Team Member
Lead Reviewer & Engineering	***Thelma Valdes, Ph.D.***
Clinical Reviewer (Effectiveness)	***Martin Golding, M.D.***
Clinical Reviewer (Safety)	***Cynthia Long, M.D.***
Statistical	Xuefeng Li, Ph.D. ***Li Ming Dong, Ph.D.***
Microbiology	Haijing Hu, Ph.D. Angel Soler-Garcia, Ph.D.
Toxicology	Xin Fu, Ph.D. Jiwen Zheng, Ph.D. Pushya Potnis, Ph.D.
Manufacturing/GMP	Cesar Perez, Ph.D.
Bioresearch Monitoring	Isatu Bah
Post Approval Study Plan	***Manuel Bayona, M.D., M.S., Ph.D.***

Meeting Agenda

- Device Indication / Description
- Regulatory History
- Non-Clinical Studies

- Clinical Presentation – Dr. Martin Golding
- Statistical Presentation – Dr. Li Ming Dong
- Clinical Presentation – Dr. Cynthia Long
- Post-Approval Study – Dr. Manuel Bayona

Proposed Indications for Use

"The TOPAS Treatment for Fecal Incontinence is intended to treat women with fecal incontinence (also referred to as accidental bowel leakage) who have failed more conservative therapies."

Device Description

- The TOPAS Treatment for Fecal Incontinence (FI) consists of:
  - Mesh Implant
  - Insertion Sheath
  - Locking Connectors
  - Insertion Needles

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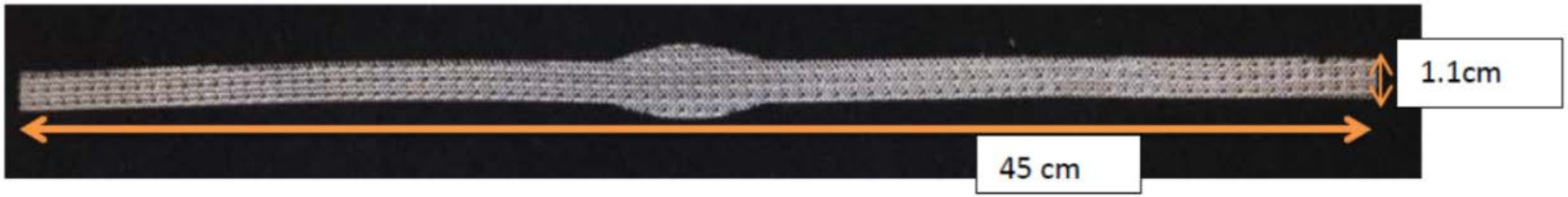

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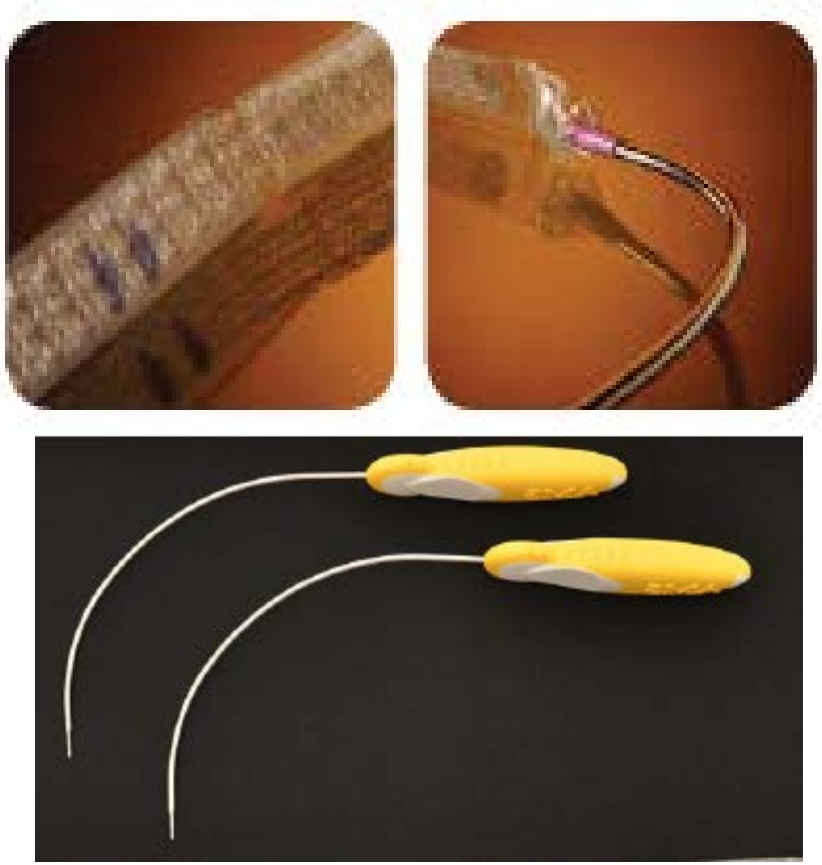

Regulatory History

- **IDE G090159 TRANSFORM Study**
  - Prospective, multi-center, single arm study (15 US Centers)
  - Intended as the pivotal study to support PMA approval; approved March 2010.
  - First implant July 2010 / Last implant Dec 2012
  - **Total 152 patients implanted**

Regulatory History

- PMA P140006
  - Filed on April 18, 2014 (AMS, Inc.)
  - Major Deficiency Letter sent to AMS, Inc: July 2014
  - Response received at FDA: July 2015
  - Major Amendment received at FDA in October 2015

Non-Clinical Studies

- Engineering/Mechanical Tests
- Sterilization and shelf life validation*
- Biocompatibility *
- Packaging Performance/Stability Testing
- TOPAS System Design Validation

FDA review is ongoing.