## FDA Review Team

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<th>Function</th>
<th>Team Member</th>
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<tr>
<td>Lead Reviewer &amp; Engineering</td>
<td>Thelma Valdes, Ph.D.</td>
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<td>Clinical Reviewer (Effectiveness)</td>
<td>Martin Golding, M.D.</td>
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<td>Clinical Reviewer (Safety)</td>
<td>Cynthia Long, M.D.</td>
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<td>Statistical</td>
<td>Xuefeng Li, Ph.D.</td>
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<td>Li Ming Dong, Ph.D.</td>
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<td>Microbiology</td>
<td>Haijing Hu, Ph.D.</td>
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<td>Angel Soler-Garcia, Ph.D.</td>
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<td>Toxicology</td>
<td>Xin Fu, Ph.D.</td>
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<td>Jiwen Zheng, Ph.D.</td>
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<td>Bioresearch Monitoring</td>
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<td>Post Approval Study Plan</td>
<td>Manuel Bayona, M.D., M.S., Ph.D.</td>
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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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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.