Speeding Innovation Through Streamlined Regulatory Tools

Brianna Prindle, restor3d

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Jan Triani, Triani Consulting

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Background and experience

Brianna Prindle

- Mid-size MDM
- Acquisition of knee company
- Infection control combination product start-up
- OSMA Board Member

HDE

Total

Talus

Jan Triani

- Big MDM experience
- Ran QA/RA at two orthopedic start-ups
- Assisted sale of client's start-up
- Medical Advisory Board Member



Existing Regulatory Tools for Novel Devices

- Humanitarian Device Exemption
- Pre-submissions
- Breakthrough Device Designation and Sprint Discussion (Previously the Expedited Access Pathway)



Humanitarian Device Exemption

- Clinical indication affects <8,000 US patients annually
- Regulatory pathway for rare disease or condition
- Proves benefit > risk
- Demonstrates safety and probable benefit, not effectiveness
- Required to submit QMS elements, supplier information and testing
- Audits of legal manufacturer part of approval process
- Post-approval study mandate is common



HDE Experience with FDA

- FDA followed precedent set by prior approval
- Received approval with a desk audit and a post approval inspection six months later
- Took two 75-day cycles since there is no 'Hold'

Q-Sub process
Custom device
retrospective
clinical data
Heavy
collaborative
interaction
Post-approval

study mandate

- HUD >Pre-Sub>HDE
- Submitted during pandemic
- 1 deficiency letter with 1 year to respond;
- Q-Subs for testing
- Think outside the box
- Supplier closed during review
- Offered creative solutions

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Pre-Submissions: Things to consider

- What is the purpose?
- Do you have feasibility data?
- Test plans or rationale?
- Timing is important

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Breakthrough Device Designation and Sprint Discussions

Process

- FDA grant/deny request for BDD in 60 calendar days
- 10 to 1 conversion rate. As of Sept 2024, CDRH granted
 1,029 BDDs with 124 achieving clearance or approval.¹
- Only 137 orthopedic BDDs granted and 17 approvals

Benefits

- Single-topic Q-subs on a 45-day cycle
- Priority review/
 management involvement
- Additional collaboration with FDA



Thank You

Brianna Prindle & Jan Triani

brianna@restor3d.com jan@trianillc.com





Thank You for Attending!

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