Medical Device Clinical investigation requirements

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s), employed by Consultancy company

I do not have any potential conflict of interest
What are the clinical investigation requirements?

EU:
MDD Annex I, X
MEDDEV 2.7.1/rev4

FDA:
Federal Food Drug and Cosmetic Act, 16 Dec 2014 (section 513, etc)
510k, 510k de Novo (Class II)
PMA (class III)
MDD93/42/EEC Essential Requirements – No. 1

The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.
Essential Requirements – No. 6 and 6a

6. Any **undesirable side-effect** must constitute an acceptable **risk** when **weighed** against the **performances** intended.

6a. Demonstration of conformity with the essential requirements must include a **clinical evaluation** in accordance with **MDD Annex X**.
US Federal Food Drug and Cosmetic Act

<<...reasonable assurance of the safety and effectiveness of the device..>>

(Class I General controls)

Class II Special controls

Class III Premarket approval

Assurance of safety and effectiveness = Clinical Evaluation
Building clinical evidence

- CER
- Clinical Investigation
- Equivalent devices
- Harmonized standards
- Design verification testing

RM

the practical approach
Bioresorbable scaffolds (BVS): clinical evaluation

<table>
<thead>
<tr>
<th>Variable</th>
<th>EU</th>
<th>US</th>
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<tbody>
<tr>
<td><strong>Abbott Absorb</strong></td>
<td></td>
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<tr>
<td>Clinical data</td>
<td>100-500 patients, 1 -3 yr</td>
<td>2250 patients</td>
</tr>
<tr>
<td>CE mark/ PMA</td>
<td>2011/12 (DEKRA)</td>
<td>June 2016</td>
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<td><strong>Elixir DESolve</strong></td>
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<tr>
<td>Clinical data</td>
<td>~120 patients</td>
<td></td>
</tr>
<tr>
<td>CE mark/ PMA</td>
<td>May 2014</td>
<td>Not yet?</td>
</tr>
<tr>
<td>On the safe side?</td>
<td></td>
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CardioBand (Valtech/ Edwards)
Cardioband™ Mitral Reconstruction System

Cardioband: CE Mark certification in September 2015

Cardioband permits physicians to repair the mitral valve in a first-line setting while preserving the option to perform future percutaneous or surgical valve repair and/or replacement. Cardioband combines a reconstruction implant, similar to surgical annuloplasty devices, with a transcatheter transseptal delivery system. Connection of the implant to the mitral annulus is sutureless, using specially designed anchors. Reshaping of the mitral annulus to eliminate FMR is done under physiological conditions and echocardiographic guidance for optimal results.

No FDA approval yet
Strengths- weaknesses

**Strengths**
- Risk based (shorter timeline)
- Clinical need
- Efficiency
- Limited budget

**Weakness**
- Haste
- Unforeseen risk
- Technology not fully developed
- Limited evidence base: healthcare does not improve
What to strengthen?

• Scrutiny
• Transparency
• Pro-active: clinical investigation in the post marketing phase
• Vigilance and post marketing surveillance
What to keep?

• Flexibility

• Sensible use of clinical evidence base

• Risk based approach (related to the characteristics of the device)

• Balancing the need for innovation and risk control
Thank you for your attention

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