Regulatory Impact of the Reclassification of Spinal Devices
Lessons Learned from Total Joint Reclassification

Itoro Udofia, PhD
Team Leader – Orthopaedic and Devices Device
October 2013
Overview

• New draft medical device regulation – spinal implants reclassification
• Implications of devices being class III
• BSI reclassification experience – total joint replacements
• Reclassification lessons learned
• Learning opportunities and resources
Draft Medical Device Regulation (MDR)

• Published September 2012
• Presentation is not intended to be a full description of the regulation and the changes
  • Many new requirements
  • Increased transparency
  • Increased clinical data requirements
  • Increased scrutiny of class III devices
  • Some reclassifications.....
Draft Medical Device Regulation (MDR)

• Updated rule 8 for implantable devices

• Rule 8:

• All implantable devices and long-term surgically invasive devices are in class IIb unless they:
  
  • ...are spinal disc replacement implants and implantable devices that come into contact with the spinal column, in which case they are class III

**WORDDING IS STILL UP FOR DEBATE**

**SPINAL COLUMN DEFINITION?**
Spinal Column Definition

- All **bones and spinal discs that comprise the spine from C1 to the coccyx**, i.e. all cervical, thoracic, lumbar and pelvic bony tissue & spinal disc elements of the spine

- Alternatively if the spinal column is interpreted as the skeletal bony tissue elements only then devices that are implanted within the spinal discs with no intention or indication for contacting the bony tissue are a potential borderline classification issue
Implications of Devices Being Class III
Manufacturer Route to CE Mark – A familiar approach?

Medical device? Device classification

General Safety and Performance Requirements (Essential Requirements)

Conformity Assessment by Notified Body (QMS & Technical documentation)

Class III Device

Annex VIII
Full Quality Assurance and Design Examination

Annex IX
Type Examination

Annex X
Product Conformity Verification

Article 44 MDCG (or ACMD) Scrutiny

NEW
Technical Documentation Assessment: Class IIb vs Class III

**Single certificate**
- Class III devices undergo an additional Design Examination (DE)
- DE certificate issued listing all product codes and variants

**Greater scrutiny**
- Increased strength of requirement for Clinical investigation and evaluation
- Greater expectation of “proactive” PMS (including PMCF)

**No sampling**
- Review is not a sampling process - all codes must be reviewed

**Review of changes**
- Substantial changes reported to Notified Body, and subject to additional review
Technical Documentation Requirements (Annex II)

New

• More detail regarding the expectations for technical documentation

Not so new (Basic contents)

• Device Description and Specification
• Information Supplied by the Manufacturer
• Design and Manufacturing Information
• General Safety & Performance Requirements
• Risk / Benefit Analysis
• Product Verification & Validation
• Pre-Clinical and clinical data
• Additional information – medicinal substances, tissues/cells of human or animal origin, method of sterilization, measuring function, connected to other devices
Clinical evaluation and clinical investigations (Chapter VI & Annex XIII & Annex XIV)

**New** - Regulation combines and incorporates current guidance's on clinical evaluation and clinical investigation

- General requirements – sponsor responsibilities
- Application
- Registration
- Electronic system
- Post market clinical investigation requirements
- Substantial modification
- Sponsor information obligations regarding suspension / termination
- Event reporting

**Not so new**

- Builds on the current Annex X of MDD
- Still allows clinical evaluation to be based on
  - critical evaluation of the literature
  - critical evaluation of results of clinical investigation
  - combination of the above
- Requires Clinical Evaluation to be updated throughout life cycle of device
Technical documentation - further reading / information

  www.ghtf.org/sg1/sq1-final.html
- NB-MED/2.5.1, “Technical Documentation” www.meddev.info/index.htm
- NBOG_BPG_2009_1, “Guidance on Design-Dossier Examination and Report Content.”
  www.nbog.eu/2.html
- BSI BoneZone Article March 2011 “Basic Anatomy of a Design Dossier”
- BSI Webinar “Basic Anatomy of a Design Dossier” – available via our website
- BSI “Creating and Maintaining Technical Files and Design Dossiers” Training Course
- BSI Technical Documentation Best Practice Guidelines (Dec 2012) available for our clients
New: Article 26 - summary of safety and clinical performance

- Draft summary of safety and clinical performance
  - For all class III and implantable devices
  - Submitted to Notified Body for review
  - Notified Body will validate
  - Must be understandable by users

- Transparency
  - Unclear as to how and where this will be made public (Eudamed ?)
NBs → Commission → MDCG of new applications for class III devices...

28 days: the MDCG may request submission of a preliminary summary

5 days: NB informs manufacturer

60 days: MDCG submits comments on summary of the preliminary conformity assessment

- Further requests possible (within 30 days - stop the clock on 60 days)
  - NB give due consideration to any comments received
  - NB shall address concerns received back from the MSCG and justify any CE decisions
  - Summary and outcome made public
- Do authorities have resources? Will they outsource? Quality of review?
**Assessment Committee for Medical Devices, ACMD (Article 44a)**

**Assessment of clinical data for high-risk devices (Special Notified Body)**

- **SNB → Commission → ACMD**
  - **20 days**: ACMD requests documentation (SNB summary report, CER, PMCF plan..)
  - **60 days**: ACMD issues opinion
    - 30 Days: ACMD requests additional information
    - ACMD may recommend modification
  - **5 days**: ACMD informs Commission, SNB and MFR of it’s opinion
  - **15 days**: SNB shall indicate if it agrees with ACMD opinion
    - 30 days: SNB may request re-examination
    - 30 days: ACMD re-examine it’s opinion
    - 15 days: ACMD shall inform Commission, SNB and MFR of it’s opinion

- **15 days**: Commission makes final decision
  - Decision will be accessible to the public

- **15 days**: Commission prepares draft decision → MS, SNB, MFR

**Proposal**
Which products under the MDR – review via Article 44

- ... novelty of the device or of the technology ...
- ... an adverse change in the risk-benefit profile of a specific category or group of devices
- ... an increased rate of serious incidents reported
- ... significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices
- ... public health concerns regarding a specific category or group of devices or the technology on which they are based
Reclassification Lessons Learned

Opportunity to share a number of lessons learned during the 2005/50/EC reclassification process
Total joint reclassification to class III – Why?

EARLY FEMORAL LOOSENING IN ONE DESIGN OF CEMENTED HIP REPLACEMENT

SAMIR N. MASSOUD, JAMES B. HUNTER, BRIAN J. HOLDSWORTH, W. ANGUS WALLACE, R. JULIUSSON

From Harlow Wood Orthopaedic Hospital, Nottingham, England

An Investigation of the Performance of the 3M™ Capital™ Hip System

July 2001


‘Small’ changes may lead to significant effects on safety and performance

Recommended a National Joint Register
Reclassification directive for total hip, knee and shoulder joints replacements

Published 2005

Enforceable for new total hip, knee and shoulder joints September 2007
- Devices required Design Dossier review and Design Examination certificate for CE Marking

Devices CE Marked prior to September 2007 – Reclassification to Class III September 2009
- Design Dossier review & Design Examination certificate issued by September 2009 to maintain CE Mark
Points to consider:

• Design Dossiers should be submitted for each family of products
• Avoid bundling multiple brands and product families into a single dossier
• Process should include Product Portfolio Strategic Planning
  • Are all spinal implants strategically important in the EU?
  • Are you planning to remove any devices in the near future?
  • Are the older and/ or low sales volume products adequately supported by design verification, PMS and clinical data?
Points to consider

• Regulations have changed since devices first placed on the market
  • Bar has been raised
  • Greater scrutiny on MFRs, NBs
• Greater emphasis on clinical and PMS data
• Less reliance on equivalence for devices with longer market history
• Submit on time
• Read the regulations
Time on market – relevant data requirements

- Good clinical data required for devices with dated design verification
- For devices that have been on the market for a number of years, clinical data on the device itself will be expected
  - PMCF Plans may well be required for devices with no clinical data for the device itself despite being on the market for a number of years
Documentation - key points

• Things change – keep up to date
  • Harmonised standards
  • Latest guidance documents
  • State of the art
  • New / updated regulations
• Keep the technical file / design dossier updated accordingly – especially:
  • Requirements Checklist
  • Post market surveillance data
  • Risk Management
  • CER
Manufacturers to use own resources

For those Spine manufacturers with Total Joint / Recon Divisions

- Network with Recon Division to share their 2005/50/EC experience and knowledge

Upcoming Technical Audits for IIa and IIb devices

- Spine manufacturers should make the most of these visits
- Key Staff who will be involved with dossier submissions could observe
- Take notes regarding any verbal comments – often become questions during design dossier reviews

Start Planning this now!

- Know what’s required
- Adequately resourced – staffing & budget
- Share plans with your NB - number of dossiers planned for submission (with brief product family descriptions); and anticipated submission dates for each dossier
BSI Orthopaedic & Dental Team

- 15 dedicated technical experts
- All with experience of design, R&D, manufacturing within the orthopaedic industry
- Diverse range of experience
- Experienced JRI re-classification process with leading orthopaedic manufacturers
## Timeline for submissions

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Start preparations (gap analysis with MDD class III &amp; new MDR)</strong></td>
<td></td>
</tr>
<tr>
<td>Early submissions possible</td>
<td>• Start performing gap assessments</td>
</tr>
<tr>
<td></td>
<td>• Talk with your NB</td>
</tr>
<tr>
<td></td>
<td>• If possible request a Class III review to assess quality of technical documentation</td>
</tr>
<tr>
<td></td>
<td>• Share your plans with your NB</td>
</tr>
<tr>
<td>Last chance for standard rate reviews</td>
<td>• Early and standard rate submissions will allow for any gaps to be identified early – and allow enough time for MFRs to address</td>
</tr>
<tr>
<td>Final submissions (@expedited rates only)</td>
<td>Only expedited rate reviews will be accepted by BSI</td>
</tr>
<tr>
<td></td>
<td>These may not complete approval in time to meet implementation date.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 - 24 months</td>
<td>Continue to share plans with NB for the duration of this period</td>
</tr>
<tr>
<td></td>
<td>BSI will continually monitor and update clients on any changes</td>
</tr>
<tr>
<td>18 months</td>
<td>Crucial for MFR to have “good quality” technical documentation – BSI can assess MFR state of readiness</td>
</tr>
<tr>
<td>6 months</td>
<td>3 months</td>
</tr>
</tbody>
</table>
Contact

Itoro Udofia, PhD
Team Leader, Medical Devices (Orthopaedic and Dental)
BSI Assurance UK Limited,
Kitemark Court, Davy Avenue, Knowlhill,
Milton Keynes, MK5 8PP, United Kingdom

T: +44 1908 814841
M: +44 776 7008367
itoroudofia.udofia@bsigroup.com