Summary of Safety and Clinical Performance

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FDANEWS

Topics

- Requirements from the MDR
- Content
- Distribution
- Questions

Requirements from the MDR

Requirements

- Applies to Class III devices and to implantable devices
- It is written to be clear to the intended user
  - If relevant, also clear to the patient
- Submit a draft to the NB as part of the application procedure
  - The NB validates the SSCP
  - The NB uploads the SSCP to Eudamed
  - The SSCP is available to the public
- The manufacturer cites the Eudamed location on the device label or in the IFU

Content

SSCP Content

- Identify the device (Basic UDI-DI) and manufacturer (SRN)
- Describe the intended purpose of the device
  - Include the target population, indications, and contraindications
- Describe the device
  - Identify any previous generations or variants
  - Describe the differences between the current version and the previous generations or variants
  - Describe any accessories, other devices, or other products intended for use with the device

SSCP Content (cont.)

- Identify possible diagnostic or therapeutic alternatives
- Include references to any harmonized standards or common specifications used
- Summarize the clinical evaluation
- Summarize relevant information from the post-market clinical follow-up
  - Relevance applies to the intended user
- Describe the suggested profile and training for the user

SSCP Content (cont.)

- Provide any information on residual risk
  - Use the risk management file. Include overall residual risk
- Provide information on undesirable effects
  - Presumable, this means undesirable side-effects
- Provide information on warnings and precautions
  - Be sure they match the label and the instructions for use

Updates

SSCP Updates

- For class III devices and implantable devices, the PMCF evaluation report and, if indicated, the SSCP referred to in Article 32 shall be updated at least annually with clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84. [Art.61(11)]

Distribution

Distribution

- Prepare the SSCP
- Submit a draft to the NB for review
  - Respond to any NB comments
- The NB validates the final SSCP
- The NB uploads the SSCP to Eudamed
- The manufacturer adds information on the SSCP availability to the label and to the instructions for use

QUESTIONS