<u>立法會CB(2)1864/17-18(02)號文件</u> LC Paper No. CB(2)1864/17-18(02)

Proposed Regulatory Framework for Medical Devices 規管醫療儀器的建議架構

 衛生署 Department of Health



Pre-market Control 推出市面前的管制

Food and Health Bureau

Department of Health

二零一八年七月十六日

食物及衞生局

16 July 2018

衞生署

□ To ensure medical devices conform with the requirements on safety, quality, performance and efficacy before allowing them to be placed on the market 在容許醫療儀器推出市面前,確保醫療儀器符合有關安全、品質、性能和效能的規定

Post-market Control 推出市面後的管制

□ To enable swift control measures against defective or unsafe medical devices 對有問題或不安全的醫療儀器迅速施加管制措施

■ Use Control 使用的管制

□ To restrict the use of specific medical devices to specified personnel 限制特定類別的人員使用某些醫療儀器





Key features

主要部份

- Pre-market and Post-market Control 推出市面前及推出市面後的管制
- Not including "Use Control"
 不包括「使用管制」
- Adjusting documentary evidence for Registration of medical devices 適度地調整醫療儀器註冊所需的證明文件
- Introducing a Transitional Listing System for medical devices 實施過渡性質的醫療儀器「表列制度」

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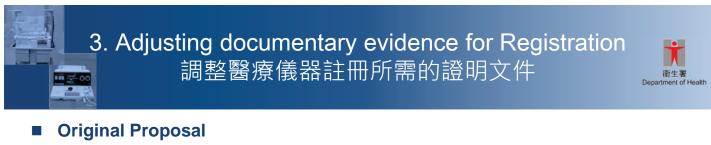
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The proposed regulatory regime will not include "Use Control" of specific medical devices
The proposed regulatory regime will not include "Use Control" of specific medical devices

建議的規管架構將不會包括特定醫療儀器的「使用管制」

 Other key jurisdictions: Use control of medical devices regulated by means other than legislation for medical devices 其他主要司法管轄區:透過醫療儀器條例以外途徑規管醫療儀器的使用

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原來建議

- Marketing approvals from 5 Global Harmonisation Task Force (GHTF) founding members: Australia, Canada, EU, Japan and the US accepted; or 接受由五個全球協調醫療儀器規管專責小組(GHTF)創始成員國監管機構發出 銷售核准證明: 澳洲、加拿大、歐盟、日本和美國;或
- Conformity Assessment Bodies (CAB) certificates accepted 接受認證評核機構發出的認證評核證書

Refined Proposal 修訂建議

□ In addition to the above, accept marketing approvals from Mainland China and South Korea in the initial phase (no CAB certificate is required) 除了上述文件, 首階段計劃接受內地及南韓的銷售核准證明 (無需認證評核證 書)

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Medical devices falling short of registration requirements can be "listed" under the "Listing System"

容許未符合註冊規定的醫療儀器可於「表列制度」下「表列」

- Active Class II or III non-invasive general medical device which may be used for modifying the anatomy or physiological process of skin of a person to enhance physical appearance
 第II或III級的非入侵性有源的一般醫療儀器,用以改變個人皮膚的結構或生理過程,以 保持、修復或改善外觀
- □ Used by beauty industry or members of the public for self-use 供美容業或市民自用的儀器
- Limit the transitional period to five years (i.e. beyond the five-year transitional window, Government will not allow new applications for devices to be listed)

為表列制度設定五年的過渡期(即為期五年的過渡期後·政府將不會接受新的醫療 儀器表列申請)

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