醫材-Final TPP

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| **No** | **TPP Attributes** | **TPP (產品現況)** | **可接受範圍(競品分析)** | **最佳範圍(產品目標)** |
| 1 | Device Description  產品敘述 | Text description • Key design features • New technology employed or the technology is fundamentally similar to a predicate device • Component parts of the medical device |  |  |
| 2 | Intended Use  適應症說明 | Clinical intended use(s) -if more than one, specify lead indication • Intended patient population • Outline clinical development plan |  |  |
| 3 | Regulatory considerations  法規途徑規劃 | Presumed path forward • Regulatory classification |  |  |
| 4 | Contraindications  禁忌症說明 | Contraindications compare with current devices or treatments for the intended use • Conditions that would put the patient in a situation where the risk of your medical device would outweigh the benefit |  |  |
| 5 | Non-clinical testing  非臨床之產品安全及有效性測試 | Identify areas where non-clinical studies would highlight how your medical device has overcome the limitations of existing devices •Biocompatibility  •Functional performance  •medicinal substance incorporated into the device (if applicable)  •biological safety of device incorporating animal or human cells, tissue or their derivatives (if applicable)  • Animal models for performance or safety be required prior to treating patients(if applicable) • Sterility (if applicable)  •Electron safety requirements and electromagnetic (if applicable)  •Software verification and validation (if applicable) |  |  |
| 6 | Clinical studies  臨床測試 | Expected outcomes of clinical studies • Clinical evidence to support the intended use • Safety profile • Endpoints in the study support the competitive positioning and marketing strategy for the new device |  |  |
| 7 | Financial considerations  財務規劃 | Basic economics: ROI, NPV • Affordability to end user • Cost of goods • Projected pricing • Cost to develop • Partners • Reimbursement |  |  |
| 8 | Intellectual property  智慧財產布局 | Path forward • Freedom to operate • Patentability |  |  |
| 9 | Competitive Environment  市場現況分析 | Analysis of competition and marketing | | |