第二等級醫療器材產品比較暨臨床前測試資料符合性聲明書
Class 2 Medical Devices Comparison and Preclinical Test Data Conformity Statement

□體外診斷醫療器材 (In Vitro Diagnostic Device, IVD)
☑非體外診斷醫療器材 (Non- In Vitro Diagnostic Device)

☑國產 Manufactured Domestically
□輸入 Imported

填寫須知：
Instructions for Filling In:

1. 本聲明書適用於第二等級醫療器材產品之查驗、變更登記，且與比較產品為相同醫療器材商、分級分類品項、製造廠、預期用途或效能或適應症、技術特點（如為體外診斷醫療器材，須具相同檢測標的、方法及臨床應用）之類似品，業經中央主管機關核准上市，且許可證仍於有效期間之產品，新申請產品內容範圍不得超過比較產品之範圍。

   This statement applies to the market approval registration and the change of registration for a Class 2 medical device, which is considered to be a similar product if its comparison product has the same medical device firm, risk class and classification item, actual manufacturing facility, intended use or effectiveness or indication, and technical characteristics (test objective, method and clinical application must be the same if it is an in vitro diagnostic device), has been approved for marketing by the central competent authority and has a license that is still within the validity period. The content scope of the new application product shall not exceed the scope of the comparison product.

2. 本聲明書各項資訊請依據醫療器材製造業者之技術性資料、安全及功能性檢驗資料據實填寫，由醫療器材製造業者之權責人員及申請醫療器材商共同簽署（如列印超出 1 頁請加蓋騎縫章戳），並保證該等資料的真實性、完整性及可追溯性。本聲明書得以替代臨床前測試及原廠品質管制之檢驗規格與方法、原始檢驗紀錄及檢驗成績書，包括為確保產品宣稱效能、結構、材質、設計及品質所進行之安全性及功能性檢測等資料。如有虛偽不實之情事，將依醫療器材管理法之相關規定論處，並應負相關法律責任。

   Please fill in each information item of this statement according to fact from the technical data, safety and performance test data of the medical device manufacturer, have it signed jointly by the medical device manufacturer's authoritative and responsible person and the medical device firm applicant (if printing more than 1 page, please stamp cross-page seal), and ensure the authenticity, integrity and traceability of those data.

   This statement may replace the preclinical testing and the test specifications and methods, the original test records, and the test reports for the quality control conducted by the original manufacturer, including documents of safety and performance testing for ensuring the claimed indication for use, structure, materials, design, and quality of the product.

If there are circumstances in which fraudulence or falsification is found, penalty shall be determined and enforced pursuant to relevant provisions of the Medical Devices Act and related legal responsibilities shall be imposed.

3. 以本聲明書申請之產品，其未檢附之臨床前測試及原廠品質管制之檢驗規格與方法、原始檢驗紀錄及檢驗成績書應留於申請醫療器材商處備查，中央衛生主管機關得要求醫療器材商於限期內提出，並依據本聲明書所載內容進行檢查判定。

   For a product applied using this statement, its preclinical testing and the test specifications and methods, the original test records, and the test reports for the quality control conducted by the original manufacturer that have not been submitted shall be kept for future reference at the premises of medical device firm. The central competent health authority may require the medical device firm to submit those documents within a prescribed period of time, and conduct inspection or make decision according to the contents declared in this statement.

4. 未依限檢附備查文件或經檢查文件內容與本聲明書所載內容不符者，視同使用虛偽不實之文件或資料申請查驗登記，將依醫療器材管理法第 69 條之規定處辦。

   Those who fail to submit within the prescribed period the documents for reference or contents of the documents have been inspected to be inconsistent with contents declared in this statement, they will be deemed as using fraudulent or falsified documents or data to apply for market approval registration, and shall be penalized and dealt with according to the provisions in Article 69 of the Medical Devices Act.

壹、新申請產品及比較產品之異同處比對表：

I. Comparative table of differences and similarities between the new application product and the comparison product

	產品資訊 **Product Information**	**新申請產品** **New Application Product**	**比較產品** **Comparison Product**	**異同處比對說明** **Comparative Explanation for Differences and Similarities**
1	中英文品名 Chinese and English Name of Product	OO 人工骨填料 “OO” Synthetic Bone Graft	XX 人工骨替代物 “XX” Bone Substitute Material	中英文品名差異
2	衛生福利部核准字號 License Number Approved by Ministry of Health and Welfare		衛部醫器製字第 OOOOOO 號	衛生福利部核准字號差異
3	製造廠名稱/地址 Manufacturer Name/Address (註：請填寫製造廠) (Note: Please fill in the actual manufacturing facility.)	食藥股份有限公司 (台北市南港區食藥路 1 號)	食藥股份有限公司 (台北市南港區食藥路 1 號)	相同
4	產品類別 Product Category	N.3045 可吸收鈣鹽骨洞填充裝置	N.3045 可吸收鈣鹽骨洞填充裝置	相同
5	產品敘述 效能/適應症/預期用途 Product Description Efficacy/Indication/Intended Use	本產品適用於填充骨缺陷，可填補因受傷、手術或口腔的骨質缺損/骨骼裂縫，其強度足以支撐患部避免凹陷，但不具有穩定骨骼	本產品可使用於填補骨骼裂縫／骨缺損(如：口腔顎面區、牙周齒槽骨、四肢、脊椎與骨盆)。當骨骼裂縫／骨缺損對骨骼結構固有	相同

		結構之功能。	的穩定性造成影響時，不適合單獨使用本材料，需配合手術中使用之固定物，加強骨骼之穩定。骨骼裂縫／骨缺損有可能來自於手術、外傷、拔牙或腫瘤清除後所造成之骨缺損。	
6	工作/設計原理/方法 Work/Design Principle/Method	本產品是以磷酸鈣鹽類為成分，具有多孔性結構的可吸收合成人工骨，在骨缺損區域提供了適合骨骼生成和骨骼組織再塑的空間。	本產品是可塑形的合成骨填補物，由 60%氫氧基磷灰石 (Hydroxyapatite; HAp) 和 40%β-磷酸三鈣 (B-tricalcium phosphate; B-TCP) 組成。本產品具有多孔性結構適合成骨細胞附著並促進骨傳導作用，本產品可於骨骼癒合期間，逐漸降解並被人體吸收，同時被新生骨所取代。	相同
7	材料/成分配方 Material/Ingredient Formula (註：適用體外診斷試劑及接觸人體之醫療器材) (Note: Applicable to medical devices that are IVD reagents and contact human body.)	磷酸鈣鹽類	磷酸鈣鹽類	相同
8	規格、型號 Model or Type	1. 型號: FR060 2. 用法: 注射型 3. 混合固化時間 -注射型: 混合 1 分鐘，靜置 2 分鐘	1. 型號: FR060 2. 用法: 注射型或塑型 3. 混合固化時間 -注射型: 混合 1 分鐘，靜置 2 分鐘	1. OO 人工骨填料用法為注射型，XX 人工骨替代物用法可選擇注射型或塑型。 2. OO 人工骨填料固化時間

		4. 保存溫度: 15-25℃	-塑型: 混合 1 分鐘，靜置 5 分鐘 4. 保存溫度: 15-25℃	為混合 1 分鐘，靜置 2 分鐘(注射型)；XX 人工骨替代物固化時間可選擇注射型(混合 1 分鐘，靜置 2 分鐘)或塑型(混合 1 分鐘，靜置 5 分鐘)。
9	使用/操作人員資格 User/Operator Qualification	專業醫護人員	專業醫護人員	相同
10	新申請產品與比較產品之差異處，不影響新申請產品臨床使用安全及效能之**說明** **Explanation** that differences between the new application product and the comparison product do not affect safety and effectiveness for clinical use of the new application product	OO 人工骨填料與 XX 人工骨替代物之用法(可選擇之固化時間)略有差異，不影響新申請產品臨床使用安全及效能。		

填寫說明：申請產品如為中央衛生主管機關已公告臨床前測試基準之品項，得參考臨床前測試基準所列之參考方法做比較。
Explanatory Note for Filling In: If the new application product is a product that has a preclinical testing guidance announced by the central health competent authority, reference methods listed in the preclinical testing guidance may be consulted for making the comparison.

貳、新申請產品之臨床前測試符合性聲明：
II. Conformity statement on preclinical testing of the new application product

產品中文名稱 Product Name in Chinese	OO 人工骨填料
產品英文名稱 Product Name in English	“OO” Synthetic Bone Graft
規格/型號 Model/Type	1. 型號: FR060 2. 用法: 注射型 3. 混合固化時間 -注射型: 混合 1 分鐘，靜置 2 分鐘 4. 保存溫度: 室溫

臨床前測試符合性聲明
Conformity Statement on Preclinical Testing

填寫說明:
Explanatory Note for Filling In:

1. 請列舉擬新申請產品符合之安全及功能性標準，標準中未訂有規格者，須另提供廠規或與類似品比對之數據資料。
   Please list and enumerate the safety and performance standards that the new application product conforms to. If there are no specifications in a standard, factory specifications or comparison data with similar products shall be provided separately.
2. 請列舉新申請產品符合之功能性試驗項目摘要
   Please list and enumerate performance test items in a summary that the new application product conforms to.

新申請產品符合之安全性及功能性標準、功能性測試摘要:
Safety and performance standards that the new application product conforms to and summary of performance tests:

表1. 新申請產品符合之安全性標準：
Table 1. Safety standards that the new application product conforms to:

序號 Order No.	評估項目 Evaluation Item	符合標準/製造廠規範 Conformity Standard / Factory Specification	報告編號 Report No.
1.	生物相容性試驗 Biocompatibility test (1)細胞毒性(Cytotoxicity)。 (2)過敏試驗(Sensitization)。 (3)刺激或皮內刺激試驗 (Irritation/ Intracutaneous reactivity)。 (4)急性毒性試驗(Acute systemic	ISO 10993-1:2018 ISO 10993-3:2014 ISO 10993-5:2009 ISO 10993-6:2016 ISO 10993-10:2021 ISO 10993-11:2017	BIO-001 BIO-002 BIO-003 BIO-004 BIO-005 BIO-006

	toxicity)。 (5)亞急性及亞慢性毒性試驗(Subacute and subchronic toxicity)。 (6)基因毒性試驗(Genotoxicity)。 (7)植入(Implantation)。		
2.	無菌 Sterility	ISO 17665:2024 ISO11135:2018 ISO11137-1:2018 ISO 11137-2:2022 ISO 11137-3:2017	ST-001
3.	熱原 Pyrogen	U.S. Pharmacopoeia National Formulary USP<151> ISO 10993-11:2017	PG-001

表2.　新申請產品符合之功能性標準及功能性試驗項目摘要：

Table 2.　Performance standards that the new application product conforms to and summary of performance test items:

序號 Order No.	測試項目 Test Item	符合標準/製造廠規範 Conformity Standard / Factory Specification	報告編號 Report No.
1	化學性質評估 Chemical Properties (1)主成分定性及定量 (2)微量不純物分析(Trace element analysis) (3)重金屬總含量不可超過 50ppm。	US FDA Guidance: Resorbable Calcium Salt Bone Void Filler Device - Class II Special Controls Guidance Document for Industry and FDA Staff (2003) ISO 13175-3(2012)	CH-001
2	物理性質評估 Physical Properties (1)結晶相的定性和定量測定(Qualitative and quantitative determination of crystalline phases)。 (2)形態、造型及其尺寸規格(Form, shape and dimensional specifications)。 (3)孔隙度(Porosity)。 (4)溶解過程和 pH 變化(Dissolution and pH change)。	US FDA Guidance: Resorbable Calcium Salt Bone Void Filler Device - Class II Special Controls Guidance Document for Industry and FDA Staff (2003) ISO 13175-3(2012)	PY-001

3	功能性試驗 Performance test (1)工作時間(Working time)。 (2)固化時間(Setting time)。 (3)尺寸穩定性(Dimensional stability)。 (4)固化反應溫度(Setting reaction temperature)。 (5)可注射性測試(Injection capability testing)/注射壓力測試(Injection pressure testing)。 (6)動物體內之降解/吸收(Resorption)評估。	US FDA Guidance: Resorbable Calcium Salt Bone Void Filler Device - Class II Special Controls Guidance Document for Industry and FDA Staff (2003) ISO 13175-3(2012)	PT-001
4	架儲期 Shelf life	US FDA Guidance: Resorbable Calcium Salt Bone Void Filler Device - Class II Special Controls Guidance Document for Industry and FDA Staff (2003) ISO 13175-3(2012) ISO 17665:2024 ISO11135:2018 ISO11137-1:2018 ISO 11137-2:2022 ISO 11137-3:2017	SF-001

新申請產品如屬體外診斷醫療器材，符合之功能性標準應至少包括以下項目：靈敏度、線性、特異性、干擾性研究、準確性、精密度/再現性、閾值確認、安定性、追溯性。
If the new application product is an in vitro diagnostic medical device, the performance standards it conforms to shall include at least the following items: sensitivity, linearity, specificity, interference study, accuracy, precision/reproducibility, threshold confirmation, stability, and traceability.

前列符合標準/製造廠規範中未訂有允收規格者，應另提供評估方法、允收規格等資料。
For the above listed conformity standards / factory specifications that do not have established acceptance specifications, information on evaluation methods, acceptance specifications, and so forth, shall be provided separately.

茲向衛生福利部切結以上所填資料均屬正確，且未檢附之臨床前測試資料均留醫療器材商處備查，如有錯誤或不實，具結醫療器材商願受許可證撤銷及醫療器材管理法規定之處分，絕無異議。
We, the undersigned, hereby declare to the Ministry of Health and Welfare, Republic of China, that

information filled out in the above is all truthful and accurate, and preclinical test data that have not been submitted are all kept for future reference at the premises of medical device firm. If there is inaccuracy or falsification, the undersigned medical device firm agrees without any objection to be subject to license revocation and penalty provisions of the Medical Devices Act.

製造廠名稱： Name of Manufacturer: 食藥股份有限公司	申請醫療器材商名稱（請蓋公司印鑑）： Name of Medical Device Firm (please stamp company seal): 食藥股份有限公司
製造廠地址： Address of Manufacturer: 台北市南港區食藥路 1 號	申請醫療器材商地址： Address of Medical Device Firm: 台北市南港區食藥路 1 號
製造廠權責人員（簽章）及日期： Authoritative and Responsible Person of Manufacturer (signature) and Date:	醫療器材商負責人(請蓋負責人印鑑)及日期： Responsible Person of Medical Device Firm (please stamp seal of the responsible person) and Date:

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