

### Appendix 3: Applicable Product Items for Class 2 Medical Device Product Comparison and Preclinical Test Data Conformity Statement

	Item Number	Name
1	A.1020	Acid phosphatase (total or prostatic) test system
2	A.1025	Adrenocorticotropic hormone (ACTH) test system
3	A.1035	Albumin test system
4	A.1050	Alkaline phosphatase or isoenzymes test system
5	A.1070	Amylase test system
6	A.1110	Bilirubin (total or direct) test system
7	A.1150	Calibrator
8	A.1345	Glucose test system
9	A.1660	Quality control material (assayed and unassayed)
10	C.5510	Immunoglobulins A, G, M, D, and E immunological test system
11	D.5630	Nebulizer
12	E.1130	Noninvasive blood pressure measurement system
13	E.2340	Electrocardiograph
14	E.2700	Oximeter
15	F.3200	Resin tooth bonding agent
16	F.3590	Preformed plastic denture tooth
17	F.3660	Impression material
18	F.4850	Ultrasonic scaler
19	F.6070	Ultraviolet activator for polymerization
20	F.6660	Porcelain powder for clinical use
21	H.5470	Ureteral dilator
22	I.0006	Medical protective clothing
23	I.4370	Surgical drape and drape accessories
24	I.4495	Stainless steel suture
25	I.4580	Surgical lamp
26	J.2800	Sterilization process indicator
27	J.2910	Clinical electronic thermometer
28	J.5440	Intravascular administration set
29	J.5570	Hypodermic single lumen needle
30	J.5860	Piston syringe
31	J.6850	Sterilization wrap
32	M.5918	Rigid gas permeable contact lens care products
33	M.5928	Soft (hydrophilic) contact lens care products
34	O.5500	Infrared lamp