

**Appendix 3: “Applicable Product Items for Class 2 Medical Device  
Product Comparison and Preclinical Test Data Conformity  
Statement” mentioned in Section 7 of the Instructions in Appendix 2**

	<b>Item Number</b>	<b>Name</b>
1	A.1020	Acid phosphatase (total or prostatic) test system
2	A.1025	Adrenocorticotrophic 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.1155	Human chorionic gonadotropin (HCG) test system
9	A.1215	Creatine phosphokinase/creatine kinase or isoenzymes test system
10	A.1345	Glucose test system
11	A.1660	Quality control material (assayed and unassayed)
12	A.1675	Blood specimen collection device
13	B.5400	Coagulation instrument
14	B.5425	Multipurpose system for in vitro coagulation studies
15	B.7470	Glycosylated hemoglobin assay
16	B.8625	Hematology quality control mixture
17	C.0002	Dengue virus serological reagents
18	C.2410	Culture medium for pathogenic Neisseria spp
19	C.3305	Herpes simplex virus serological reagents
20	C.3390	Neisseria spp. Direct serological test reagents
21	C.3860	Trichomonas vaginalis nucleic acid assay
22	C.5100	Antinuclear antibody immunological test system
23	C.5270	C-reactive protein immunological test system
24	C.5510	Immunoglobulins A, G, M, D, and E immunological test system
25	C.5750	Radioallergosorbent (RAST) immunological test system
26	C.5775	Rheumatoid factor immunological test system
27	D.5630	Nebulizer
28	D.5710	Electrically powered oxygen tent
29	D.5730	Tracheal tube

30	D.5800	Tracheostomy tube and tube cuff
31	D.5915	Manual emergency ventilator
32	E.0005	Percutaneous transluminal coronary angioplasty (PTCA) catheter
33	E.1130	Noninvasive blood pressure measurement system
34	E.1200	Diagnostic intravascular catheter
35	E.1210	Continuous flush catheter
36	E.1220	Electrode recording catheter or electrode recording probe
37	E.1280	Steerable catheter
38	E.1310	Vessel dilator for percutaneous catheterization
39	E.1330	Catheter guide wire
40	E.1340	Catheter introducer
41	E.1650	Angiographic injector and syringe
42	E.2340	Electrocardiograph
43	E.2360	Electrocardiograph electrode
44	E.2700	Oximeter
45	E.2900	Patient transducer and electrode cable (including connector)
46	E.3450	Vascular graft prosthesis
47	E.4450	Vascular clamp
48	E.5150	Embolectomy catheter
49	E.5900	Thermal regulating system
50	F.1745	Laser fluorescence caries detection device
51	F.1800	Extraoral source x-ray system
52	F.1810	Intraoral source x-ray system
53	F.3060	Gold based alloys and precious metal alloys for clinical use
54	F.3200	Resin tooth bonding agent
55	F.3275	Dental cement
56	F.3590	Preformed plastic denture tooth
57	F.3630	Endosseous dental implant abutment
58	F.3660	Impression material
59	F.3690	Tooth shade resin material
60	F.3765	Pit and fissure sealant and conditioner
61	F.3820	Root canal filling resin
62	F.4760	Bone plate
63	F.4850	Ultrasonic scaler
64	F.6070	Ultraviolet activator for polymerization
65	F.6660	Porcelain powder for clinical use

66	G.4250	Ear, nose, and throat electric or pneumatic surgical drill
67	H.1075	Gastroenterology-urology biopsy instrument
68	H.1500	Endoscope and accessories
69	H.4620	Ureteral stent
70	H.5010	Biliary catheter and accessories
71	H.5130	Urological catheter and accessories
72	H.5470	Ureteral dilator
73	H.5540	Blood access device and accessories
74	H.5630	Peritoneal dialysis system and accessories
75	H.5820	Hemodialysis system and accessories
76	H.5980	Gastrointestinal tube and accessories
77	I.0003	Ultrasonic surgical instrument
78	I.0006	Medical protective clothing
79	I.4010	Tissue adhesive
80	I.4014	Nonresorbable gauze/sponge for external use
81	I.4018	Hydrophilic wound dressing
82	I.4020	Occlusive wound/burn dressing
83	I.4022	Hydrogel wound dressing and burn dressing
84	I.4370	Surgical drape and drape accessories
85	I.4400	Electrosurgical cutting and coagulation device and accessories
86	I.4493	Absorbable poly(glycolide/L-lactide) surgical suture
87	I.4495	Stainless steel suture
88	I.4580	Surgical lamp
89	I.4780	Power suction pump
90	I.4810	Laser surgical instrument for use in general and plastic surgery and in dermatology
91	I.4830	Absorbable surgical gut suture
92	I.4840	Absorbable polydioxanone surgical suture
93	I.5000	Nonabsorbable poly (ethylene terephthalate) surgical suture
94	I.5010	Nonabsorbable polypropylene surgical suture
95	I.5020	Nonabsorbable polyamide surgical suture
96	I.5030	Natural nonabsorbable silk surgical suture
97	I.5035	Nonabsorbable expanded polytetrafluoroethylene surgical suture
98	J.2800	Sterilization process indicator
99	J.2910	Clinical electronic thermometer
100	J.5090	Liquid bandage

101	J.5200	Intravascular catheter
102	J.5240	Medical adhesive tape and adhesive bandage
103	J.5440	Intravascular administration set
104	J.5570	Hypodermic single lumen needle
105	J.5700	Neonatal phototherapy unit
106	J.5860	Piston syringe
107	J.5965	Subcutaneous, implanted, intravascular infusion port and catheter
108	J.5970	Percutaneous, implanted, long-term intravascular catheter
109	J.6850	Sterilization wrap
110	K.4305	Powered compound cranial drills, burrs, trephines, and their accessories
111	K.4310	Powered simple cranial drills, burrs, trephines, and their accessories
112	K.4360	Electric cranial drill motor
113	K.4370	Pneumatic cranial drill motor
114	K.4840	Manual rongeur
115	L.1690	Hysteroscope and accessories
116	L.1720	Gynecologic laparoscope and accessories
117	L.1730	Laparoscopic insufflator
118	L.4150	Bipolar endoscopic coagulator-cutter and accessories
119	L.6100	Assisted reproduction needles
120	L.6110	Assisted reproduction catheters
121	L.6130	Assisted reproduction microtools
122	M.1120	Ophthalmic camera
123	M.1570	Ophthalmoscope
124	M.1850	AC-powered slitlamp biomicroscope
125	M.4150	Vitreous aspiration and cutting instrument
126	M.4670	Phacofragmentation system
127	M.4790	Ophthalmic sponge
128	M.5918	Rigid gas permeable contact lens care products
129	M.5925	Soft (hydrophilic) contact lens
130	M.5928	Soft (hydrophilic) contact lens care products
131	N.1100	Arthroscope
132	N.3027	Polymethylmethacrylate (PMMA) bone cement
133	N.3045	Resorbable calcium salt bone void filler device
134	N.3050	Spinal interlaminar fixation orthosis

135	N.3060	Spinal intervertebral body fixation orthosis
136	N.3070	Pedicle screw spinal system
137	O.0001	Static electric therapy apparatus
138	O.3860	Powered wheelchair
139	O.5500	Infrared lamp
140	P.1570	Diagnostic ultrasonic transducer