「醫療器材產品基準採認清單」(102.3.)

編號	採認基準編號	適用類別	基準發佈組織	發佈年份	產品基準名稱	備註	採認基準公告文號
1	TFDA-G-00001	A類臨床化學及臨床毒理學	美國FDA	2004	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry(2004)		
2	TFDA-G-00002	A類臨床化學及臨床毒理學	美國FDA	2000	Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers(2000)		
3	TFDA-G-00003	A類臨床化學及臨床毒理學	美國FDA	1999	Guidance for Industry: Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators(1999)		
4	TFDA-G-00004	A類臨床化學及臨床毒理學	美國FDA	2000	Guidance for Industry and FDA Reviewers/Staff: Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s(2000)		
5	TFDA-G-00005	A類臨床化學及臨床毒理學	美國FDA	1998	Guidance for Industry: In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System(1998)		
6	TFDA-G-00006	A類臨床化學及臨床毒理學	美國FDA	1998	Guidance for Industry: In Vitro Diagnostic Chloride Test System(1998)		

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7	TFDA-G-00007	A類臨床化學及臨床毒理學	美國FDA	1998	Guidance for Industry: In Vitro Diagnostic Creatinine Test System(1998)		
8	TFDA-G-00008	A類臨床化學及臨床毒理學	美國FDA	2002	Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA(2002)		
9	TFDA-G-00009	A類臨床化學及臨床毒理學	美國FDA	1998	Guidance for Industry: In Vitro Diagnostic Glucose Test System(1998)		
10	TFDA-G-00010	A類臨床化學及臨床毒理學	美國FDA	1998	Guidance for Industry: In Vitro Diagnostic Potassium Test System(1998)		
11	TFDA-G-00011	A類臨床化學及臨床毒理學	美國FDA	2007	Guidance for Industry and FDA Staff: Assayed and Unassayed Quality Control Material(2007)		
12	TFDA-G-00012	A類臨床化學及臨床毒理學	美國FDA	1998	Guidance for Industry: In Vitro Diagnostic Sodium Test System(1998)		
13	TFDA-G-00013	A類臨床化學及臨床毒理學	美國FDA	1998	Guidance for Industry: In Vitro Diagnostic Urea Nitrogen Test System(1998)		
14	TFDA-G-00014	A類臨床化學及臨床毒理學	美國FDA	2005	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems(2005)		

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15	TFDA-G-00015	A類臨床化學及臨床毒理學	美國FDA	2003	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Breath Nitric Oxide Test System(2003)		
16	TFDA-G-00016	A類臨床化學及臨床毒理學	美國FDA	2005	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Drug Metabolizing Enzyme Genotyping System(2005)		
17	TFDA-G-00017	A類臨床化學及臨床毒理學	美國FDA	2004	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Sirolimus Test Systems(2004)		
18	TFDA-G-00018	B類血液學及病理學	美國FDA	1998	Guidance for Industry: Guidance for Submission of Immunohistochemistry Applications to the FDA(1998)		
19	TFDA-G-00019	ABC類體外診斷醫材	美國FDA	2007	Guidance for Industry and FDA Staff: Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions(2007)		
20	TFDA-G-00020	B類血液學及病理學	美國FDA	2001	Class II Special Controls: Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA Document issued(2001)		

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21	TFDA-G-00021	B類血液學及病理學	美國FDA	2003	Guidance for Industry and FDA Staff: 510(k) Submissions for Coagulation Instruments(2003)		
22	TFDA-G-00022	B類血液學及病理學	美國FDA	2007	Guidance for Industry and FDA Staff: Review Criteria for Assessment of Qualitative Fecal Occult Blood In Vitro Diagnostic Devices(2007)		
23	TFDA-G-00023	B類血液學及病理學	美國FDA	2004	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems(2004)		
24	TFDA-G-00024	B類血液學及病理學	美國FDA	1999	Guidance for Industry and FDA Reviewers/Staff: In Vitro Diagnostic Fibrin Monomer Paracoagulation Test(1999)		
25	TFDA-G-00025	C類免疫學及微生物學	美國FDA	2011	Guidance for Industry and FDA Staff: Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses(2011)		
26	TFDA-G-00026	C類免疫學及微生物學	美國FDA	1997	REVJEW CRITERIA FOR ASSESSMENT OF ANTIMICROBIAL SUSCEPTIBILITY TEST DISCS(1997)		
27	TFDA-G-00027	C類免疫學及微生物學	美國FDA	2009	Guidance for Industry and FDA: Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems(2009)		

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28	TFDA-G-00028	C類免疫學及微生物學	美國FDA	2004	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan(2004)		
29	TFDA-G-00029	C類免疫學及微生物學	美國FDA	2003	Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Endotoxin Assay(2003)		
30	TFDA-G-00030	C類免疫學及微生物學	美國FDA	2011	Guidance for Industry and Food and Drug Administration Staff: Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays(2011)		
31	TFDA-G-00031	C類免疫學及微生物學	美國FDA	2006	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses(2006)		
32	TFDA-G-00032	C類免疫學及微生物學	美國FDA	2007	Guidance for Industry and FDA Staff: In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path(2007)		
33	TFDA-G-00033	C類免疫學及微生物學	美國FDA	2003	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus(2003)		

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34	TFDA-G-00034	C類免疫學及微生物學	美國FDA	2005	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: RNA Preanalytical Systems (RNA Collection, Stabilization and Purification Systems for RT-PCR used in Molecular Diagnostic Testing)(2005)		
35	TFDA-G-00035	C類免疫學及微生物學	美國FDA	2005	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems(2005)		
36	TFDA-G-00036	C類免疫學及微生物學	美國FDA	2009	Guidance for Industry and FDA Staff: Recommendations for Anti-Nuclear Antibody (ANA) Test System Premarket (510(k)) Submissions(2009)		
37	TFDA-G-00037	C類免疫學及微生物學	美國FDA	2006	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems(2006)		
38	TFDA-G-00038	C類免疫學及微生物學	美國FDA	2005	Guidance for Industryand FDA Staff: Review Criteria for Assessment of C-Reactive Protein (CRP), High Sensitivity C-Reactive Protein (hsCRP) and Cardiac C-Reactive Protein (cCRP) Assays(2005)		

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39	TFDA-G-00039	D類麻醉科	美國FDA	2001	Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA(2001)		
40	TFDA-G-00040	D類麻醉科	美國FDA	2000	Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer(2000)		
41	TFDA-G-00041	D類麻醉科	美國FDA	2002	Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA(2002)		
42	TFDA-G-00042	D類麻醉科	美國FDA	2002	Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO2) and Oxygen (PcO2) Monitors; Guidance for Industry and FDA(2002)		
43	TFDA-G-00043	E類心臟血管醫學	美國FDA	2010	Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems (2010)		
44	TFDA-G-00044	E類心臟血管醫學	美國FDA	2003	Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm (2003)		
45	TFDA-G-00045	E類心臟血管醫學	美國FDA	1998	Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance (1998)		

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46	TFDA-G-00046	E類心臟血管醫學	美國FDA	1997	Non-Invasive Blood Pressure (NIBP) Monitor Guidance (1997)		
47	TFDA-G-00047	E類心臟血管醫學	美國FDA	2008	Guidance for Industry and FDA Staff: Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (2008)		
48	TFDA-G-00048	E類心臟血管醫學	美國FDA	2003	Guidance for Industry and FDA Staff: Coronary and Peripheral Arterial Diagnostic Catheters(2003)		
49	TFDA-G-00049	E類心臟血管醫學	美國FDA	1995	Guidance on Premarket Notification [510(K)] Submission for Short-Term and Long-Term Intravascular Catheters (1995)		
50	TFDA-G-00050	E類心臟血管醫學	美國FDA	1998	Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm) (1998)		
51	TFDA-G-00051	E類心臟血管醫學	美國FDA	1998	Diagnostic ECG Guidance (Including Non-Alarming ST Segment Measurement) (1998)		
52	TFDA-G-00052	E類心臟血管醫學	美國FDA	1997	Electrocardiograph (ECG) Lead Switching Adaptor (1997)		
53	TFDA-G-00053	E類心臟血管醫學	美國FDA	1997	Guidance for Electrocardiograph(ECG) Electrode (1997)		

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54	TFDA-G-00054	E類心臟血管醫學	美國FDA	1997	Guidance Document: Device-Electrocardiograph(ECG) Surface Electrode Tester (1997)		
55	TFDA-G-00055	E類心臟血管醫學	美國FDA	1997	General Guidance Document: Non-Invasive Pulse Oximeter (1997)		
56	TFDA-G-00056	E類心臟血管醫學	美國FDA	2006	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Implantable Intra-Aneurysm Pressure Measurement System (2006)		
57	TFDA-G-00057	E類心臟血管醫學	美國FDA	2004	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices (2004)		
58	TFDA-G-00058	E類心臟血管醫學	美國FDA	1999	Guidance for Industry and FDA Reviewers/Staff: Guidance for Cardiovascular Intravascular Filter 510(k) Submissions (1999)		
59	TFDA-G-00059	E類心臟血管醫學	美國FDA	2000	Guidance for Industry and FDA Staff: Guidance Document for Vascular Prostheses 510(k) Submissions (2000)		

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60	TFDA-G-00060	E類心臟血管醫學	美國FDA	2000	Guidance for Industry: Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions (2000)		
61	TFDA-G-00061	E類心臟血管醫學	美國FDA	2001	Guidance for Annuloplasty Rings 510(k) Submissions; Final Guidance for Industry and FDA Staff (2001)		
62	TFDA-G-00062	E類心臟血管醫學	美國FDA	2000	Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final Guidance for Industry and FDA (2000)		
63	TFDA-G-00063	E類心臟血管醫學	美國FDA	2000	Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions; Final Guidance for Industry and FDA (2000)		
64	TFDA-G-00064	E類心臟血管醫學	美國FDA	2000	Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff (2000)		
65	TFDA-G-00065	L類婦產科學	美國FDA	1996	Hysteroscopes and Gynecologic Laparoscopes: Submission Guidance for a 510(k) (1996)		
66	TFDA-G-00066	L類婦產科學	美國FDA	1978	Guidelines of Evaluation of Hysteroscopic Sterilization Devices (1978)		

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67	TFDA-G-00067	L類婦產科學	美國FDA	1995	Hysteroscopic And Laparoscopic Insufflators: Submission Guidance For A 510(K)(1995)		
68	TFDA-G-00068	L類婦產科學	美國FDA	2008	Guidance for Industry and FDA Staff: Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (2008)		
69	TFDA-G-00069	L類婦產科學	美國FDA	2001	Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors (2001)		
70	TFDA-G-00070	L類婦產科學	美國FDA	1995	Guidance on the Content and Organization of a Premarket Notification for a Medical Laser (1995)		
71	TFDA-G-00071	L類婦產科學	美國FDA	1998	Guidance for Industry: Latex Condoms for Men, Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions (1998)		
72	TFDA-G-00072	L類婦產科學	美國FDA	2005	Guidance for Industry and FDA Staff: Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) (2005)		
73	TFDA-G-00073	L類婦產科學	美國FDA	2000	Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance Document for Clitoral Engorgement Devices (2000)		

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74	TFDA-G-00074	L類婦產科學	美國FDA	2004	Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Assisted Reproduction Laser Systems (2004)		
75	TFDA-G-00075	O類物理醫學科	美國FDA	1995	Guidance Document for The Preparation of Premarket Notification [510(K)] Applications for Electromyograph Needle Electrodes(1995)		
76	TFDA-G-00076	O類物理醫學科	美國FDA	1999	Guidance Document for Powered Muscle Stimulator 510(k)s(1999)		
77	TFDA-G-00077	O類物理醫學科	美國FDA	2006	Guidance for Industry and FDA Staff: Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment(2006)		
78	TFDA-G-00078	O類物理醫學科	美國FDA	1995	Guidance Document for the Preparation of Premarket Notification [510k] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles(1995)		
79	TFDA-G-00079	O類物理醫學科	美國FDA	1995	Guidance Document for The Preparation of Premarket Notification [510(K)] Applications for Immersion Hydrobaths(1995)		
80	TFDA-G-00080	O類物理醫學科	美國FDA	1995	Guidance Document for The Preparation of Premarket Notification [510(K)] Applications for Exercise Equipment(1995)		

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81	TFDA-G-00081	O類物理醫學科	美國FDA	1995	Guidance Document for The Preparation of Premarket Notification [510(K)] Applications of Submerged (Underwater) Exercise Equipment(1995)		
82	TFDA-G-00082	O類物理醫學科	美國FDA	1995	Guidance Document for The Preparation of Premarket Notification [510(K)] Applications For Heating and Cooling Devices(1995)		
83	TFDA-G-00083	P類放射學科類	美國FDA	1998	Guidance for Industry: Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices(1998)		
84	TFDA-G-00084	P類放射學科類	美國FDA	2008	Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Bone Sonometers(2008)		
85	TFDA-G-00085	P類放射學科類	美國FDA	1998	Guidance for Industry: Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems(1998)		
86	TFDA-G-00086	P類放射學科類	美國FDA	1998	Guidance for Industry: Guidance for the Submission of Premarket Notifications For Radionuclide Dose Calibrators(1998)		

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87	TFDA-G-00087	P類放射學科類	美國FDA	1999	Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance: Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices(1999)		
88	TFDA-G-00088	P類放射學科類	美國FDA	2000	Guidance for the Submission Of Premarket Notifications for Medical Image Management Devices(2000)		
89	TFDA-G-00089	P類放射學科類	美國FDA	2008	Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions(2008)		
90	TFDA-G-00090	P類放射學科類	美國FDA	2007	Guidance for Industry and FDA Staff: Compliance Guide for Cabinet X-Ray Systems(2007)		