

LIST OF RISK CLASIFICATION OF MEDICAL DEVICE

NO	PRODUCTS	4th AMDTC Notes	
		CLASS	REMARK
CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES			
1	Artificial Pancreas Device System, Threshold Suspend	C	
HEMATOLOGY AND PATHOLOGY DEVICES			
2	System, Test, Blood Typing Test	C	Except for ABO system [A (ABO1), B (ABO2), AB (ABO3)], rhesus system [RH1(D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)], Kell system [Kel1 (K)], Kidd system [JK1 (Jka), JK2 (Jkb)] and Duffy system [FY1 (Fya), FY2 (Fyb)] determination which are classified as Class D
IMMUNOLOGY AND MICROBIOLOGY DEVICES			
3	Assay, Genotype, Hiv Drug Resistance, In Vitro	C	
4	Enzyme Linked Immunosorbent Assay, T. Cruzi	C	
5	Test, Equipment, Automated Bloodborne Pathogen	A	
CARDIOVASCULAR DEVICES			
6	Barrier, Adhesion, Cardiovascular	D	
7	Cardiovascular Catheter Sheath Introducer Kit	B	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
8	Catheter, Peripheral, Atherectomy	B	
9	Clip, Vascular	B	Unless they are long-term surgically invasive medical devices, are in Class C; Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D

10	Compressor, Cardiac, External	A	Unless they are active medical device, in which case they are in Class B; Unless they are specifically intended for therapy the vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, in which case they are in Class C
11	Dc-Defibrillator, High Energy, (Including Paddles)	C	Unless they are surgically invasive, in which case they are in Class D
12	Device, Vascular, For Promoting Embolization	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
13	Device. Laser Peripheral Angioplasty	B	Unless this is done in a manner that is potentially hazardous with higher power, in which case they are in Class C; Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
14	Endovascular Suturing System	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
15	Fibrillator, Ac	C	Unless they are surgically invasive, in which case they are in Class D
16	Glue,Surgical,Arteries	C	Unless they are absorbable, in which case they are in Class D

17	Graft, Vascular, Synthetic/Biologic Composite	C	Unless they are manufactured from or incorporating with animal cells, tissues and/or derivatives thereof, rendered nonviable, or cells, tissues and/or derivatives of microbial or recombinant origin are Class D
18	Graft,Vascular,Stainless Steel Tunneler	B	
19	Kit, Balloon Repair, Catheter	B	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
20	Material, Embolization, Neurovascular, Polymerizing Or Precipitating	D	
21	Polymerizing, Neurovascular Embolization Material	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
22	Programmer, Pacemaker	C	
23	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, and/or they are manufactured from or incorporating with animal cells, tissues and/or derivatives thereof, rendered nonviable, or cells, tissues and/or derivatives of microbial or recombinant origin, in which case they are in Class D
24	Prosthesis, Vascular Graft, Of Less Than 6mm Diameter	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, and/or they are manufactured from or incorporating with animal cells, tissues and/or derivatives thereof, rendered nonviable, or cells, tissues and/or derivatives of microbial or recombinant origin, in which case they are in Class D

25	Pulse Generator, External Pacemaker, Dual-Chamber	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
26	Pulse-Generator, Pacemaker, External	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
27	Pulse-Generator, Single Chamber, Single	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
28	Shunt, Portosystemic, Endoprosthesis	C	
29	Stent, Iliac	D	
30	Stent, Renal	C	
31	Stent, Superficial Femoral Artery	C	
32	Suture, Cardiovascular	D	
33	System, Catheter Or Guidewire, Steerable (Magnetic)	B	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
34	System, Esophageal Pacing	B	
35	Tissue Graft Of 6mm And Greater	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, and/or they are manufactured from or incorporating with animal cells, tissues and/or derivatives thereof, rendered nonviable, or cells, tissues and/or derivatives of microbial or recombinant origin, in which case they are in Class D

36	Tissue Graft Of Less Than 6mm	C	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, and/or they are manufactured from or incorporating with animal cells, tissues and/or derivatives thereof, rendered nonviable, or cells, tissues and/or derivatives of microbial or recombinant origin, in which case they are in Class D
37	Transducer, Pressure, Catheter Tip	B	
38	Transducer, Vessel Occlusion	B	Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D
DENTAL DEVICES			
39	Adhesive, Denture, Acacia And Karaya With Sodium Borate > 12% By Weight	A	
40	Adhesive, Denture, Karaya With Sodium Borate	A	
41	Cord, Retraction	A	
42	Resin, Root Canal Filling Containing Chloroform	B	
EAR, NOSE, AND THROAT DEVICES			
43	Device, Antichoke, Suction	A	Unless they are active medical device, in which case they are in Class B
44	Paste, Injectable For Vocal Cord Augmentation	C	Unless they are absorbable, and/or they are manufactured from or incorporating with animal cells, tissues and/or derivatives thereof, rendered nonviable, or cells, tissues and/or derivatives of microbial or recombinant origin, in which case they are in Class D

