



DEVICE DETAILS

NAME OF DEVICE	RAINBOW PULSE OXIMETER
ESTABLISHMENT NAME	NYPRAX BUSINESS SOLUTIONS
REGISTRATION NO	GC430321043618
DESCRIPTION	THE RADICAL-7 PULSE CO-OXIMETER IS A NONINVASIVE MONITOR THAT MEASURES ARTERIAL OXYGEN SATURATION (SPO ₂), PULSE RATE (PR), AND PERFUSION INDEX (PI), ALONG WITH OPTIONAL MEASUREMENTS OF HEMOGLOBIN (SPHB)*, CARBOXYHEMOGLOBIN (SPCO)*, TOTAL OXYGEN CONTENT (SPOC), METHEMOGLOBIN (SPMET)*, PLETH VARIABILITY INDEX (PVI), OXYGEN RESERVE INDEX (ORI)*, ACOUSTIC RESPIRATION RATE (RRA)*, AND PLETH RESPIRATION RATE (RRP)*.
DEVICE GROUPING TYPE	Family
INTENDED PURPOSE	THE RADICAL-7 PULSE CO-OXIMETER CAN BE USED AS EITHER A HANDHELD OR A STANDALONE MONITOR. THE RADICAL-7 PULSE CO-OXIMETER FEATURES A TOUCHSCREEN THAT CONTINUOUSLY DISPLAYS NUMERIC VALUES FOR ARTERIAL OXYGEN SATURATION (SPO ₂), PULSE RATE (PR), AND PERFUSION INDEX (PI), ALONG WITH OPTIONAL MEASUREMENTS OF HEMOGLOBIN (SPHB)*, CARBOXYHEMOGLOBIN (SPCO)*, TOTAL OXYGEN CONTENT (SPOC), METHEMOGLOBIN (SPMET)*, PLETH VARIABILITY INDEX (PVI), OXYGEN RESERVE INDEX (ORI)*, ACOUSTIC RESPIRATION RATE (RRA)*, AND PLETH RESPIRATION RATE (RRP)*.
VALIDITY DATE OF REGISTRATION	29-06-2018 - 28-06-2023

LIST OF DEVICE

#	NAME OF DEVICE	IDENTIFIER
1	Rad-97	9738
2	Rad-97 NiBP	9797
3	Rad-97 with Nomoline Capnography	9799
4	Radical-7	9500
5	Radical Docking Station, RDS-1	9021
6	Radical Docking Station, RDS-3	9023
7	Rad-67	9794
8	Pronto Spot Check Pulse CO-Oximeter	9167

#	NAME OF DEVICE	IDENTIFIER
9	Radius-7	9664
10	Rad-57 Configurable Pulse CO-Oximeter	9216
11	Masimo RainbowSET IntelliVue Module	3924
12	Root	9515
13	Root NIBPT	9695
14	rainbow RC-12, rainbow Patient Cable, 12 ft	2404
15	rainbow RC-1, rainbow Patient Cable, 1 ft	2405
16	rainbow RC-4, rainbow Patient Cable, 4 ft	2406
17	M-LNC-1, M-LNCS Series Patient Cable, 1 ft	2523
18	M-LNC-4, M-LNCS Series Patient Cable, 4 ft	2524
19	M-LNC-10, M-LNCS Series Patient Cable, 10 ft	2525
20	M-LNC-14, M-LNCS Series Patient Cable, 14 ft	2526
21	M-LNC-10-GE, M-LNCS to GE Patient Cable, 10 ft	2533
22	M-LNC-04-DB9, M-LNCS to DB9 Patient Cable, 4 ft	2534
23	M-LNC-10-DB9, M-LNCS to DB9 Patient Cable, 10 ft	2535
24	M-LNC-14-DB9, M-LNCS to DB9 Patient Cable, 14 ft	2536
25	M-LNC-4-GE, M-LNCS to GE Patient Cable, 4 ft	2655
26	M-LNC-SL-10, M-LNCS to Spacelab Patient Cable, 10 ft	2714
27	M-LNC-MP10, M-LNCS to IVM / MMS, 10 ft	2831
28	RC25-12, rainbow Patient Cable, 12 ft	3342
29	RC25-12RA, rainbow Patient Cable, 12 ft	3343
30	RC25-4RA, rainbow Patient Cable, 4 ft	3375
31	M-LNCS Patient Cable, Red M-LNCv-4	3513
32	M-LNCS Patient Cable, Red M-LNCv-10	3514
33	RC25-4, rainbow Patient Cable, 4 ft	3628
34	M-LNC MP4, M-LNCS to IVM / MMS, 4 ft	3754

#	NAME OF DEVICE	IDENTIFIER
35	RC25-1, rainbow Patient Cable, 1ft	3933
36	RC25-1RA, Patient Cable, 1ft	3934
37	M-LNC-10-NK, M-LNCS to NK Patient Cable, 10 ft	3985
38	rainbow M20-01, rainbow Patient Cable, 1 ft	4236
39	rainbow M20-04, rainbow Patient Cable, 4 ft	4237
40	rainbow M20-12, raionbow Patient Cable, 12 ft	4238
41	rainbow RC-1 EMS, Patient Cable, 1/box	4480
42	rainbow RC-4 EMS, Patient Cable, 1/box	4481
43	rainbow RC25-1 EMS, Patient Cable, 1/box	4482
44	rainbow RC25-4 EMS, Patient Cable, 1/box	4483
45	rainbow RC25-1RA EMS, Patient Cable, 1/box	4484
46	rainbow RC25-4RA EMS, Patient Cable, 1/box	4485
47	spo2.com NRC-180 Patient Cable	1810
48	spo2.com NRC-395 Patient Cable	1811
49	spo2.com NRC-P12, Patient Cable	1853
50	spo2.com NRC-GE Patient Cable	1854
51	spo2.com NRC-SL , Spacelabs Replacement Cable	1900
52	spo2.com NRC-P8, Patient Cable, 3M	1949
53	spo2.com NRC-SL2 Spacelabs Replacement Cable	2335

