

**Appendix 2: Medically Necessary Devices**

<b>Device Name</b>	<b>K Number / Exempt Status</b>	<b>Product Code</b>
EncoreAnywhere	K091319	BZD
BiPAP S/T ventilatory support system intended for use by lower weight patient populations (40-66 lbs) in accordance with the controls agreed upon by SRC and FDA	K102465	MNS
BiPAP AVAPS ventilatory support system intended for use by lower weight patient populations (40-66 lbs) in accordance with the controls agreed upon by SRC and FDA	K102465	MNS
Disposable/FEP/Invasive Circuits	K982454	MNT
Body Position Sensor - Dx	K940013	MNR
Cannula Style Thermocouples	K913396	BZG
Care Orchestrator	K181053	MNT; CAW; BZD; CBK; NOU
Care Orchestrator Essence;	K183226	MNS; MNT; BZD; CBK; NOU
Care Orchestrator Essence 4.3 USB Release;	K183226	MNS; MNT; BZD; CBK; NOU
Care Orchestrator Essence, Japan	K183226	MNS; MNT; BZD; CBK; NOU
Care Orchestrator;	K152356	BZD; CBK; MNS; MNT; NOU
DreamMapper	K152356	BZD; CBK; MNS; MNT; NOU
CPAP VALVES	K950397	BYE
Crystal Trace Piezo Sensor	K923402	BZQ
Disposable 22mm non-heated passive and heated active circuits;	Exempt	BZO
Disposable 15 mm non-heated passive and heated active circuits;	Exempt	BZO
Disposable 15mm MPV circuit	Exempt	BZO
Disposable Adult/Ped Heated Active Circuit;	K110398	BZE
Disposable Heated Wire Circuits;	K110398	BZE
Disposable Adult/Ped Heated Passive Circuit	K110398	BZE
Drain, Tee (water trap)	Exempt	BYH

PC Direct;	K090539	MNS
Omnilab Direct;	K090539	MNS
ECG electrode	K991105	DRX
ECG wireset;	K040595	OLV; OLZ
Sleepware G3;	K040595	OLV; OLZ
Sleepware;	K040595	OLV; OLZ
Encore/Encore Pro Data Management System;	K010263	BTT; BZD
EncoreAnywhere;	K092818	MNS
Flow Sensor;	K963380	BZC
FloTrak CO2 Sensor	K963380	BZC
DirectView Data Management System;	K121623	MNT
Encore Anywhere;	K121623	MNT
Universal Battery Pack (UBP2);	K121623	MNT
OMNILAB DIRECT	K121623	MNT
H2 Heated Humidifier	K030090	BTT
Heated Humidifier - MR850	K073706	BTT
Masimo MS Series	K100428	DQA
Mouthpiece, Angled;	Exempt	BYP
Mouthpiece, Straight;	Exempt	BYP
Mouthpiece, Angled Disposable;	Exempt	BYP
Mouthpiece, Reusable	Exempt	BYP
Multiple - Invasive;	Exempt	CAE
Flex Trach Adaptor 15 cm, 22M/15F-15F;	Exempt	CAE
Flex Trach Adaptor 15 cm, 22M/15F-22F	Exempt	CAE
Opti Chamber Valved Holding Chamber	K962822	CAF
OptiChamber Diamond with Lite Touch mask	K110293	NVP
Passover Humidifier	K945782	BTT
Patient Circuits	Exempt	CAI
Performance Tubing 6'	K140424	BZE
Performance Tubing;	Exempt	BYX
Low Range Cabinet Flow Meter;	Exempt	BYX
Oxygen Manifold Kit	Exempt	BYX
PLM Sensor	K940014	BZQ
Pressure Valve	K963250	BZD
Pro-Flow and Pro-Flow Plus Cannula Sensors;	K982293	MNR
Pressure Transducer Airflow Sensor (PTAF);	K982293	MNR
PTAF 2, 3, Lite	K982293	MNR
Remote Alarm	K913423	CBK
REMstar Heated Humidifier;	K090243	BZD
Encore Pro 2 Data Management System;	K090243	BZD
Universal Battery Pack (UBP2)	K122769	BZD
Respironics Disposable Heated Wire Circuits;	K110398	BZE

Disposable Adult/Ped Heated Active Circuit;	K110398	BZE
Disposable Adult/Ped Heated Passive Circuit	K110398	BZE
Roll Stand, DreamStation 2;	Exempt	FOX
Roll Stand, DreamStation;	Exempt	FOX
Roll Stand, BiPAP A-series;	Exempt	FOX
Roll Stand, OmniLab Advanced +;	Exempt	FOX
Roll Stand, Trilogy Evo;	Exempt	FOX
Wheelchair Mount, Trilogy Evo;	Exempt	FOX
Mounting Bracket, Trilogy Evo ;	Exempt	FOX
Roll Stand, SPRS-2 (H-111 cm);	Exempt	FOX
Mount, EV300	Exempt	FOX
Sleepmapper;	Exempt	OUG
Payer Integration Software;	Exempt	OUG
Omnilab Connect;	Exempt	OUG
AOM;	Exempt	OUG
Encore Basic;	Exempt	OUG
DreamStation Cellular Modem;	Exempt	OUG
DreamStation Wi-Fi Accessory;	Exempt	OUG
HL7 Interface Utility;	Exempt	OUG
DreamStation Link Module;	Exempt	OUG
PR1 Wired/Wireless Modems	Exempt	OUG
Sleepware G3 Event Detection Software	K142988	MNR; OLV; OLZ
Snoring Microphone	K940015	MNR
Thermistor Cannula Style	K960851	BZQ
Trilogy Nurse Call Adaptor Cable	K083526	CBK
DirectView Data Management System;	K093416	CBK
Trilogy Nurse Call Adaptor Cable	K093416	CBK
Universal Battery Pack (UBP2);	K093905	CBK
Trilogy Nurse Call Adaptor Cable	K093905	CBK
Trilogy Nurse Call Adaptor Cable;	K181170	CBK
Dual Limb Active Exhalation Valve;	K181170	CBK
Nurse Call Adaptor Cable – Alarm Open/Closed;	K181170	CBK
Nurse Call Rj9 Adapter Cable Open;	K181170	CBK
12/24V Battery Cable w/terminals or adapter;	K181170	CBK
External Flow Sensor Assembly Adult/Pediatric;	K181170	CBK
External Flow Sensor Assembly Pediatric/Infant	K181170	CBK
Trilogy Nurse Call Adaptor Cable;	K181166	CBK; NOU
Dual Limb Active Exhalation Valve;	K181166	CBK; NOU
Nurse Call Adaptor Cable – Alarm Open/Closed;	K181166	CBK; NOU
Nurse Call Rj9 Adapter Cable Open;	K181166	CBK; NOU
12/24V Battery Cable w/terminals or adapter;	K181166	CBK; NOU

External Flow Sensor Assembly Adult/Pediatric;	K181166	CBK; NOU
External Flow Sensor Assembly Pediatric/Infant;	K181166	CBK; NOU
Universal Battery Pack (UBP2);	K113053	MNS
DirectView Data Management System;	K113053	MNS
ProChamber Valved Holding Chamber	K032809	CAF
CoughAssist	K002598	NHJ
CoughAssist;	K122111	BYI; NHJ
Simply Clear	K122111	BYI; NHJ
Cough Assist T70	K121955	NHJ
Esprit/V200 Ventilator with APRV Option	K110083	CBK
Everflo/Everflo Q/L4;	K061261	CAW
OPI and non-OPI;	K061261	CAW
EverFlo Quiet;	K061261	CAW
Transfill;	K061261	CAW
Ultrafill Quiet;	K061261	CAW
EverFlo;	K061261	CAW
Everflo Ultrafill	K061261	CAW
A40 Heated Humidifier;	K121623	MNT
SimplyGo POC;	K111885	CAW
SimplyFlo POC;	K111885	CAW
SimplyGo Mini POC	K111885	CAW
Trilogy 100 BT International;	K083526	CBK
Trilogy 100 Ventilator;	K083526	CBK
Garbin Ventilator BT;	K083526	CBK
Trilogy 100 Ventilator BT, U.S.;	K083526	CBK
Trilogy EC Ventilator;	K083526	CBK
Trilogy 200 Ventilator;	K093416	CBK
Trilogy 200 Ventilator BT;	K093416	CBK
Trilogy 200 Ventilator BT International;	K093416	CBK
Garbin Plus Ventilator;	K093416	CBK
Trilogy 202 Ventilator;	K093905	CBK
Trilogy Evo Universal Ventilator;	K181170	CBK
Trilogy Evo Ventilator;	K181166	CBK; NOU
Trilogy EV300	K181166	CBK; NOU
A30 Heated Humidifier;	K113053	MNS
V200 Ventilator	K102054	CBK
V200 Ventilator with Intelli-Trak Option	K110795	CBK
V60 Ventilator	K082660	MNT
V60 with PPV and Auto-Trak +	K102985	MNT
Assess Low Range Peak Flow Meter	K902292	BZH
Asthma Check;	K962925	BZH

Peak Flow Meter	K962926	BZH
Chest Shell and components	K895849	BYT
Heated Humidifier - HC100	K915460	BTT
Heated Humidifier - HC500	K953392	BTT
Heated Humidifier - MR410	K913367	BTT
Millenium M10;	K043006	CAW
OPI & non-OPI;	K043006	CAW
Millennium Transfill	K043006	CAW
NEV-100	K910947	BYT
Oasis Humidifier	K964653	BTT
Quantum Respiratory Effort Sensor	K913395	BZG
SmartSleep, Deep Sleep Headband	Exempt	HCC
Stardust 2; Stardust I, II	K052573	MNR