

510(k) Number (if known): _____

Device Name: Multicompatible EnviteC Disposable and Reusable Oximeter Sensor(s)

Indications for use:

Continuous or spot monitoring of non-invasive arterial oxygen saturation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K992215

Prescription Use ☒
(Per 21 CFR801.109)

OR

Over the Counter Use _____

3

(Optional Format 1-2-96)