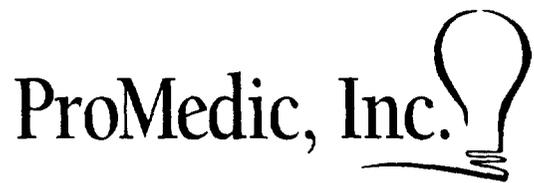


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Official contact: Paul Dryden, President

Proprietary or Trade Name: Burlew Infant Hood

Common/Usual Name: Infant hood

Classification Name: 73 BYL or FOG - Infant oxygen tent / hood
Subsection 868.5700

Intended device: Disposable Infant hood with drape

Predicate devices: Nova Health Systems - K893713
Sunnydale - K# unknown
Utah Medical - Disposa-Hood - K# unknown

Device description:

Indicated use:

The device indicated for patients who need to be placed in an oxygen enriched environment.

Target Population:

Neonates and pediatrics

Environment of use:

Hospital, ICU (neonatal and pediatric), respiratory therapy and transport isolettes / incubators

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Comparison to predicate devices:

Attribute	Burlew Intended device	Nova / Sunnydale Tent	Utah Medical Disposa-Hood
Use			
Intended for use with patient for an oxygen rich environment	Yes	Yes	Yes
Intended for use in RT	Yes	Yes	Yes
Indicated for use in ICU	Yes	Yes	Yes
Intended to be used in transport	Yes	No	No
Indicated for single patient use	Yes	Yes	Yes
Indicated for use with neonate and pediatric	Yes	Yes	Yes
Design			
Clear patient area	Yes	Yes	Yes
Fittings for connection to oxygen source	Yes	Yes	Yes
Different sizes	Yes	Yes	Yes
Flexible drape to cover patient	Yes	Yes	No
Collapsible for easy storage	Yes	No	No
Panel removable for easy patient access	Yes	Yes	No
Materials			
Plexiglas / polycarbonate hood	Yes	No	Yes
PVC drape	Yes	Yes	No
Performance Testing			
None applicable	Yes	Yes	Yes

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Differences

The only difference in the intended device is that it incorporates the feature of the two predicate into one device - a rigid patient hood and flexible body drape.

Any other differences that do exist would not have a significant effect on the safety or effectiveness of the device.