

K962874

FEB 25 1997

510(K) SUMMARY

RESPIFLO/S

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Date this Summary was prepared: July 16, 1996

Trade Name:

RESPIFLO/S

Common Name:

Sterile Water with Saline for Inhalation Therapy

Classification Name:

Sterile Water with Saline for Inhalation Therapy

Legally Marketed Devices in Which Substantial Equivalence is claimed:

Hudson RCI AQUAPAK/S

Description of the Device: This product is Sterile Water with Saline for Inhalation Therapy. It is packaged in a closed system and it is disposable after one use. The water is sterile and endotoxin free according to the USP. The product is used for Inhalation and Humidification during Inhalation Therapy.

Intended Use of the Device: For Inhalation and Humidification by way of Sterile Water in a closed system during Inhalation Therapy.

Summary of Technological Characteristics: This product is the exact same in nature and design as a currently marketed in the United States as the product used for Inhalation and Humidification during Inhalation Therapy.

Summary of Test Data:

Sterile Water with Saline according to the USP
Endotoxin free
3 year and 5 year Stability Testing
Closed system and disposable, single use

See Test Data Results in Section 11, "Confidential Testing, Methods and Results."