

K962872

FEB 25 1997

**510(K) SUMMARY**

**RESPIFLO**

**Applicant:**

Kendall GmbH  
Raffineriustrasse 18  
93333  
Neustadt an der Donau  
Germany

Contact: Mr. Konrad Schmitt

Telephone: 09445/959/160  
FAX: 09445/959/189

**Submitted by:**

Curtin & Associates International, Inc.  
1200 East Street  
Dedham, MA 02026

Contact: Mr. William D. Curtin

Telephone: 1.617.329.1955  
FAX: 1.617.329.2529

Date this Summary was prepared: July 16, 1996

**Trade Name:**

RESPIFLO

**Common Name:**

Sterile Water for Inhalation Therapy

**Legally Marketed Devices in Which Substantial Equivalence is claimed:**

**Hudson RCI AQUAPAK**

**Description of the Device:** This product is Sterile Water 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 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."***