K960593

ARADIGM

MAY 10 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

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1. **Submitter's Information:** Dated: 01/31/96

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2. **Proprietary Name:** **SmartMist™** Asthma Management System, consisting of

   i. **SmartMist™** Controller, model number SM-100

   ii. **SmartMist™** Spirometry Airway, model number SA-100

   Common or Usual Name: Metered dose inhaler accessory / peak flow meter

   Classification Name: Accessory, Metered Dose Inhaler, classification unknown / Meter, peak flow, spirometry, 21 CFR § 868.1860

3. **Predicate Devices:**

   i. MEDTRAC Technologies, Inc. PeakLog™ Peak Flow Meter, K940835

   ii. Vitalograph Inc. A.I.M. - Aerosol Inhalation Monitor, K893665

   iii. Monaghan Medical AeroChamber® MDI Accessory, K872037

4. **Description of Device:**

The Aradigm Corporation **SmartMist™** Asthma Management System is a single patient use prescribed metered dose inhaler (MDI) accessory and peak flow meter. The **SmartMist™** is composed of the non-disposable, battery powered, portable **SmartMist™** Controller and the **SmartMist™** Spirometry Airway. In addition to its primary purpose of assisting with drug delivery and its secondary purpose of monitoring lung function, a tertiary function of patient compliance monitoring is available.

The **SmartMist™** Asthma Management System is designed to work with a particular style of MDI, without modification. The entire MDI--canister and plastic actuator--is inserted into the **SmartMist™** without the introduction of any flaps or valves. The MDI is easily removed for cleaning or for manual dosing should the **SmartMist™** become inoperable.

As the patient inhales through their prescribed MDI that they have inserted into the **SmartMist™**, the device's microprocessor monitors the inhalation flow rate and volume detected by the system's pressure transducer. If the inhalation flow rate and volume fall within

the factory programmed parameters, the microprocessor triggers its mechanism to actuate the MDI canister; aerosol medication is delivered to the patient.

Feedback regarding the inhalation flow rate is provided to the patient in the form of red and green LEDs. When the green LED is illuminated, the patient is breathing at the recommended inhalation rate for aerosol drug delivery.

The **SmartMist™** Asthma Management System also functions as an electronic peak flow meter. When the user exhales through the Spirometry Airway, the device's microprocessor determines the peak expiratory flow rate (PEFR) and forced expiratory volume in one second (FEV_1). The peak flow rate is displayed to the patient in the liquid crystal display window.

A record of PEFR, FEV_1, and dosing (inhalation) events is stored in the **SmartMist™** memory for later retrieval, if desired, by a trained medical practitioner. Therefore, the **SmartMist™** also provides patient compliance monitoring at the option of the practitioner.

Use of MDI medications with the **SmartMist™** provides to the patient continual inhalation technique training. Since the **SmartMist™** will not deliver the medication unless the patient's inhalation is at the proper flow rate, the patient receives technique feedback each time the **SmartMist™** is used for delivery of medication. Red and green indicators provide easily understood flow rate feedback to the patient.

5. Statement of Intended Use:

The Aradigm Corporation **SmartMist™** Asthma Management System is intended for use by asthma patients who self medicate with metered dose inhalers (MDI) and who measure peak expiratory flow rate (PEFR) as part of their asthma management programs.

6. Statement of Technological Characteristics:

The **SmartMist™** Asthma Management System has no significant change in design, materials, energy source or other technological characteristics compared to the predicate devices. The **SmartMist™** Asthma Management System is similar in function to other such devices. The **SmartMist™** combines functions that historically have been available to patients only as separate device. The **SmartMist™**, then, is compared to three separate predicate devices: the MDI medication delivery functions of the **SmartMist™** are compare to the Monaghan Medical AeroChamber® MDI Accessory; the spirometry functions are compared to the MEDTRAC Technologies PeakLog™ Peak Flow Meter; and the training functions are compared to the Vitalograph A.I.M. Aerosol Inhalation Monitor.

As an accessory to MDI medication delivery, the **SmartMist™** differs from the predicate in that the **SmartMist™** is an active electromechanical device rather than a passive mechanical device. For the spirometry functions, the primary difference is the method of pressure measurement. Whereas the predicate device utilizes heated wire technology, the **SmartMist™** utilizes solid-state pressure transducer technology. For the training functions, the **SmartMist™** trains the patient each time they use the device to inhale their MDI medication. The predicate device only trains in the practitioner's office using a custom placebo MDI.

7. Summary of Testing:

In addition to standard device testing, such as that found in the *Reviewer Guidance for Respiratory Device* and the *Reviewer Guidance for Computer Controlled Medical Devices*, the **SmartMist™** was tested against the American Thoracic Society recommended standards for monitoring spirometry and was tested for the average weight of a metered spray from an MDI. The results of the testing show that **SmartMist™** meets the ATS recommendations and delivers a spray which is within the accepted standards.