

K 961894

AUG 14 1996

510(k) SUMMARY
for
MDI Tutor Inc.'s MDI Tutor

1. DATE PREPARED

May 15, 1996

2. SPONSOR INFORMATION

Address: MDI Tutor, Inc.
782 West Euclid
Palatine, IL 60067

Contact: Dr. Jeffry W. Kreamer
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3. DEVICE NAME

Proprietary Name: MDI Tutor
Common/Usual Name: Metered Dose Inhaler Monitoring Accessory
Classification Name: Accessory to Medicinal Nonventilatory Nebulizer (Atomizer)

4. DEVICE DESCRIPTION AND INTENDED USE

The MDI Tutor is intended for use as an accessory to metered dose inhalers (MDIs) to assist the user by monitoring the inhalation cycle and providing positive feedback (an auditory whistle) to corroborate correct inspiratory technique. The device is a simple plastic cylinder designed to fit flush over the mouthpieces of inhalers supplied by Schering (Proventil and Vanceril), Allen and Hanburys (Ventolin and Serevent), and Warrick (Albuterol). A whistle mechanism on the device is activated by the user during inspiration. The accessory device does not introduce additional space to the metered dose inhaler or interfere with the performance of the inhaler. The whistle reminds the user to sustain a slow continuous inspiration when using the metered dose inhaler.

5. COMPARISON TO PREDICATE DEVICES

The MDI Tutor is similar in design, function, and intended use to the whistles found on the AeroChamber® and the InspirEase® devices; both are accessories to metered dose inhalers. The whistles on these devices are also intended to help the patient monitor his/her own inspiratory cycle. The devices differ only in the manner of monitoring; the predicate devices whistle when the patient is breathing too quickly, whereas the MDI Tutor whistles when the patient is breathing correctly, thereby reminding the patient to sustain a continuous inspiration following actuation of the MDI. The whistles on the AeroChamber® and InspirEase® devices are incorporated on spacer attachments for metered dose inhalers, whereas the MDI Tutor is not.

6. DEVICE TESTING

Performance testing for the MDI Tutor was designed to determine the threshold pressure required to evoke the whistle (.13 L/sec). Results of the testing confirmed the suitability of the device for its intended use.