This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

1/13/94 DRAFT 510(k) submission requirements for Peak Flow Meters which supplement the Draft Reviewer Guidance for Premarket Notification submissions.

1. Provide a tabular comparison or features, components, materials, specifications, and indications between your device and other legally marketed devices. This should include the devices ranges and accuracy, and method of measurement. Any differences in your comparison should be accompanied with a discussion of the rationale for the new item, feature, or specification, and data demonstrating that no new issues of safety and effectiveness are raised.

2. Explain how calibration of the device is accomplished and provide data demonstrating this.

3. Provide the following information as specified in section II of the National Asthma Education Program's Statement on Technical Standards for peak flow meters:

   a. Please provide the test procedure, results, and a summary the accuracy and reproducibility using the waveform 24 parameters.

   b. Please provide the test procedure, results, and a summary that demonstrates the device has reproducibility within 10 liters per minute or +/- 5% of reading.

   c. Please provide the test procedure, results and a summary that demonstrates the inter-device variability within +/-5%.

   d. Please provide test procedures, results, and a summary relating to the device life span and durability.

   Test procedures, data, and results should be provided with this information. Please note that the data should be provided for a statistically significant number of devices.

4. Demonstrate compliance with the Guidance for Peak Flow Meters for Over the Counter Use, or include prescription labeling which states "Caution: Federal Law restricts this device to sale by or on the order of a physician." All labeling, including promotional advertising and claims, must be provided in either case.

5. If the device includes software/firmware, provide software specifications and design information as well as a discussion of the software development process, testing and data showing that all requirements were met. Please refer to the Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review.