

K963035



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Non-Confidential Summary of Safety and Effectiveness
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Proprietary or Trade Name: Micro Spirometer

Common/Usual Name: Diagnostic Spirometer

Classification Name: 73 BZG - Diagnostic Spirometer

Intended device: Diagnostic spirometer

Predicate devices: Spirometrics Model 2600 Micro Spirometer - K901057

Device description: A hand-held portable electronic spirometer measuring FEV1 and FVC.

Indicated use:

The intended device takes spirometer readings of a patient during exhalation. The output readings are FEV1 and FVC.

Targeted population:

Patients requiring lung function evaluations.

Environment of use:

Places where a qualified clinican desires to take these lung measurements - FEV1 and FVC.

Comparison to predicate devices:

Attribute	Intended device	Spirometrics Model 2600
Use		
Intended as a spirometer	Yes	Yes
Intended to measure lung function FEV1 and FVC	Yes	Yes

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Comparison to predicate devices: (continued)

Attribute	Intended device	Spirometrics Model 2600
Use (continued)		
Indicated for measuring patients lung function	Yes	Yes
Indicated for use by a clinician in environments such as the home or hospital	Yes	Yes
Manufactured by Micro Medical	Yes	Yes
Exact same unit as supplied to and marketed by Spirometrics and approved under K901057	Yes	--
Design		
Transducer - flow sensing turbine	Yes	Yes
No output	Yes	Yes
Flow range lps BTPS 0-12	Yes	Yes
Volume range liters 0-9.99	Yes	Yes
Measures - FVC - FEV1	Yes	Yes
Accuracy + / - 3	Yes	Yes
Display LCD	Yes	Yes
Transducer cleaned after use	Yes	Yes
Utilizes paper mouthpiece	Yes	Yes
Materials		
Same materials as K901057	Yes	Yes
Performance Testing		
None applicable	Yes	Yes

Differences

There is no difference between the intended device and the listed predicate device.