

Device Name

Common Name: Electronic Nebulizer

Proprietary Name: eFlow®

Classification Name: Nebulizer

Marketing Clearance

The eFlow Electronic Nebulizer was cleared by the Food and Drug Administration on May 5, 2004.

510(k) Number: K033833

Device Description

The PARI eFlow® is a small, single patient use, reusable electronic nebulizer for the inhalation treatment of aerosol medications. It is a hand-held device containing a capped medication cup that can be filled by the user. Power input is provided by either 4 AA batteries, a DC adapter or a AC adapter. Alternate power cords/plugs/adapters allow use in any country.

Non-Clinical Test Summary

The eFlow® Electronic Nebulizer was tested to compare performance to the predicate devices, including:

- MMAD: eFlow MMAD is comparable to or lower than predicate devices
- RF: eFlow RF is comparable to or greater than predicate devices
- TOR: eFlow TOR is comparable to or greater than predicate devices
- Safety EMC: eFlow meets the requirements of EN/IEC 60601-1, DIN EN 60601-2 and UL 1431

Clinical Performance Summary

Clinical testing was not completed/is not required to show substantial equivalence.

Conclusions from Testing

The eFlow meets performance requirements and raises no new issues of safety or effectiveness.

Intended Use

The eFlow is a handheld nebulizer that will be used with patients for whom doctors have prescribed medication for nebulization. The eFlow is intended for adult and pediatric patients.

The eFlow SCF has not undergone human clinical studies with any medication to establish safety or efficacy. The FDA has not approved any combination of a medication with the eFlow SCF device as a drug/device combination.