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510(k) SUMMARY
As Required by 807.92(c)

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1. **Submitter:** DHD Diemolding Healthcare Division
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2. **Device Name**

- Trade Name - TheraPEP[®]
- Common name - Positive Expiratory Pressure (PEP) device
- Classification name - Incentive Spirometer - 868.5690

3. **Predicate Device:** DHD TheraPEP (addition to claims only).

4. **Device Description**

The DHD TheraPEP is a single-patient-use Respiratory Therapy device. The standard system consists of a resistor, pressure range indicator, pressure port adapter, and mouthpiece. The mask may be substituted for the mouthpiece. Pressure monitoring is optional, and the pressure port adapter is removable.

5. **Intended Use**

The DHD TheraPEP is intended for use as a Positive Expiratory Pressure Device for patients suffering from Cystic Fibrosis, lung diseases with secretory problems, *and to prevent or reverse atelectasis.* (Note that added claims are indicated in italics.)

6. **Technological Information**

No technological changes - submission is only to add claim.

7. **Summary of Studies**

The clinical data (reference documents) supporting the added claims show that PEP therapy is effective for prevention and reversal of atelectasis.

8. **Conclusions Drawn from Studies**

The added indication (to prevent or reverse atelectasis) for PEP therapy will not adversely affect the safety and effectiveness of the TheraPEP device when utilized for this application as TheraPEP is approved for PEP therapy.