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Non-Confidential Summary of Safety and Effectiveness
March 1, 1996

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Official contact: Tom Dielmann, Director, Regulatory Affairs / Quality Assurance

Proprietary or Trade Name: Gas Sampling Interface Kits

Common/Usual Name: Disposable Gas Sampling Lines

Classification Name: Analyzer, Gas, Carbon Dioxide, Gaseous Phase

Intended device: Gas Sampling Interface Kits

Predicate devices: Gibeck, Inc. - disposable gas sampling lines - K841722

Device description: The intended product is a small bore tube with luer fittings which permit a sample of patient's expired gas to be delivered to an analyzer. The device may be of various lengths, tubing diameters and have an in-line filter.

Intended use:

Indicated use - When a sample of a patient's expired gas is to be analyzed.

Targeted population - Any patient requiring monitoring of expired gases.

Environment of use - Hospital, anesthesia, ICU, PACU, respiratory therapy

Comparison to predicate devices:

Attribute	Marquest	Dryden (Gibeck)
Use		
Indicated for use with expired gas sampling monitors	Yes	Yes

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(continued)

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Comparison to predicate devices: (continued)

Attribute	Marquest	Dryden (Gibeck)
Use (continued)		
Intended for use in anesthesia	Yes	Yes
Intended for use in respiratory therapy	Yes	Yes
Indicated for single use	Yes	Yes
Design		
Luer fittings	Yes	Yes
Clear	Yes	Yes
Various diameters of tubing	Yes	Yes
Various lengths of tubing	Yes	Yes
Maybe supplied with filter	Yes	Yes
Materials		
Luers made of PVC, PC, ABS, Acrylic	Yes	Yes
Tubing - PVC, PE, PVC/PE	Yes	Yes
Performance Testing		
Luer fittings	Yes	Yes

B. Differences

Any differences that do exist would not have a significant effect on the safety or effectiveness of the device.