

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k120247

B. Purpose for Submission:

New accessory to a glucose device

C. Measurand:

D-glucose values

D. Type of Test:

Glucose tolerance beverage

E. Applicant:

Vineland Syrup, Inc.

F. Proprietary and Established Names:

EasyDeX

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1345; Glucose test system
2. Classification:
Class II
3. Product code:
MRV; Drink, Glucose Tolerance
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
See Indications for use below.
2. Indication(s) for use:
EasyDex is a flavored non-carbonated beverage containing specific quantities of dextrose (D-glucose). The manufactured beverages contain three (3) different quantities of glucose: 50, 75, and 100 grams quantities per 10 oz. bottle. This product is used in the administration of an in Vitro Diagnostic Glucose Tolerance Test in the evaluation of diabetes mellitus and other related disease conditions. This product is for oral consumption only.

3. Special conditions for use statement(s):
For prescription use only

4. Special instrument requirements:
None

I. Device Description:

The EasyDeX glucose tolerance beverage is a water-based flavored beverage containing specific quantities of dextrose (d-glucose). The product is manufactured in 2 flavors (fruit punch and orange) and 3 concentrations per flavor (50, 75, 100 grams).

J. Substantial Equivalence Information:

1. Predicate device name(s):
Glucose Tolerance Beverage

2. Predicate K number(s):
k032753

3. Comparison with predicate:

	<u>Candidate Device</u> Vineland Syrup EasyDeX Glucose Tolerance Beverage	<u>Predicate Device</u> PERK Scientific Glucose Tolerance Beverage (k032753)
Intended use	Same	The Glucose Tolerance Beverage is intended to be used as an accessory to an oral glucose tolerance test in the evaluation of diabetes mellitus and related disease conditions.
Sugar Composition	Same	Dextrose
Concentrations	Same	50, 75, 100 grams
Bottle	Same	Plastic
Cap	Same	Tamper Evident Band
Flavors	Same	Orange, Fruit Punch
Carbonation	Same	No
Shelf Life	Same	18 months
Bottle Size	Same	10 ounces
Lot Number/Expiration Date	Printed on Container	Printed on Bottle Neck

K. Standard/Guidance Document Referenced (if applicable):

None

L. Test Principle:

This product is used in the administration of the oral glucose tolerance test. Patients are instructed not to eat or drink anything after midnight before the test. After the glucose load is consumed, blood samples are drawn for glucose measurements at specific time intervals to determine potential defects in insulin secretion and/or insulin action. Fifty gram glucose loads are typically administered for the initial screening of gestational diabetes. Seventy-five gram glucose loads are typically administered for the diagnosis of diabetes mellitus. One hundred gram glucose loads are typically administered for the diagnosis of gestational diabetes.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Not Applicable

- b. *Linearity/assay reportable range:*
Not applicable
- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability:

Not applicable

Stability:

As part of the shelf life evaluation studies, stability studies included sugar composition and microbiological (yeast and molds) testing at various intervals on all 6 products (flavors/concentrations).

Stability study protocols and acceptance criteria were reviewed and found acceptable. Real time stability studies are ongoing.

Expected Values:

Not applicable

- d. *Detection limit:*
Not applicable
- e. *Analytical specificity:*
Not applicable
- f. *Assay cut-off:*
Not applicable

2. Comparison studies:

- a. *Method comparison with predicate device:*
Not applicable
- b. *Matrix comparison:*
Not applicable

3. Clinical studies:

- a. *Clinical Sensitivity:*
Not applicable
- b. *Clinical specificity:*
Not applicable
- c. *Other clinical supportive data (when a. and b. are not applicable):*
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.