CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-314

Microbiology Review(s)

MICROBIOLOGY REVIEW

DIVISION OF SPECIAL PATHOGENS AND IMMUNOLOGIC DRUG PRODUCTS (HFD-590)

NDA #: 21-314

REVIEWER:	Peter A. Dionne
CORRESPONDENCE DATE:	02-FEB-01
CDER DATE:	02-FEB-01
REVIEW ASSIGN DATE:	21-FEB-01
REVIEW COMPLETE DATE:	21-MAR-01

SPONSOR: Oridion Medical 1987 Ltd.
P.O. Box 45025, HaMarpe7
Jerusalem, 91450 Israel

US Agent: [redacted]

SUBMISSION REVIEWED: Original NDA

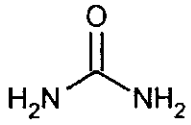
DRUG CATEGORY: ^{13}C-urea breath test for detection of *H. pylori* infection

INDICATIONS: Detection of *Helicobacter pylori* infection

DOSAGE FORM: ^{13}C-urea (75 mg tablet)

DRUG PRODUCT NAME

PROPRIETARY: Oridion BreathID™ system
NONPROPRIETARY/USAN: ^{13}C-urea breath test
CHEMICAL NAME: ^{13}C-urea
STRUCTURAL FORMULA:



Molecular Formula: CH_4N_2O
Molecular Weight: 60.06

BACKGROUND:

The intended use of the Oridion BreathID™ system is to continually and non-invasively measure changes in the $^{13}CO_2/^{12}CO_2$ ratio of exhaled breath. This may be indicative of increased urease production associated with active *Helicobacter pylori* infection in the stomach.

The Oridion BreathID™ breath test is a non-radioactive, *in vivo*, diagnostic test for the identification of patients with *H. pylori* infection. The test continually and non-invasively samples the patient's breath before (baseline) and after the ingestion of the ^{13}C-enriched urea substrate and measures the changes in the $^{13}CO_2/^{12}CO_2$ ratio. Changes from baseline are displayed as a graph on the device screen. The device software has a predictive algorithm that continually analyzes the trend of measured results and determines if the final delta over baseline (DOB) measurements will be positive or negative. When the predictive algorithm determines that the final value will be greater or less than 5 DOB the test is stopped. A positive result is a final reading of DOB >5. A negative result is a DOB <5.

There are no microbiological issues involved in this application.

CONCLUSIONS:

There are no microbiological issues involved with this product or in the clinical trials performed with the product. A microbiology review is, therefore, not needed for this application.

RECOMMENDATIONS:

There are no microbiological comments to send to the sponsor..

/S/

Peter A. Dionne
Microbiologist HFD-590

CONCURRENCES:
HFD-590/Div Dir_____Signature_____Date
HFD-590/TLMicro_____Signature_____Date

CC:
HFD-590/Original NDA # 21-134
HFD-550/Division File
HFD-590/Micro/PDionne
HFD-590/MO/JMeyer
HFD-590/Pharm/SHundley
HFD-590/Chem/GHolbert
HFD-590/CSO/LChen

/s/

Peter Dionne
3/23/01 08:09:19 AM
MICROBIOLOGIST

Shukal signed on 3/22/01--Ken signed 3/22/01

Shukal Bala
3/23/01 08:12:43 AM
MICROBIOLOGIST

Kenneth Hastings
4/11/01 11:14:48 AM
PHARMACOLOGIST