September 30, 2022

Nasogastric Feeding Solutions, Ltd.
% Crystal Koelper
President
Koelper Consulting, LLC
268 Biltmore Drive
North Barrington, IL 60010

Re: K212316
Trade/Device Name: DoubleChek DC-1001
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: KNT
Dated: August 27, 2022
Received: August 29, 2022

Dear Crystal Koelper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212316

Device Name
DoubleChek DC-1001

Indications for Use *(Describe)*
Intended Use:
DoubleCHEK is intended to indicate whether the tip of a naso/oro gastric tube tip is in an acidic or CO2 environment during or after initial placement.

The DoubleCHEK is NOT intended to confirm the location of the naso/oro gastric tube.

Indications for Use:
The DoubleCHEK is indicated for use with an initially placed or an in-situ naso/oro gatric tube. It is intended to indicate whether the tip of a naso/oro gastric tube is in an acidic or CO2 environment during or after initial placement. It is NOT intended to confirm the location of the naso/oro gastric tube.

The device is intended to be used by Health Care Professionals on all patients within a health care setting.
The device is intended to be used with a single patient for up to 24 hours.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary of Safety and Effectiveness

Submitter / 510(k) Holder

Company:	NasoGastric Feeding Solutions, Ltd. doing business as Enteral Access Technologies, Ltd.
Address:	131 Mount Pleasant Liverpool L3 5TF Great Britain
Phone:	+44 151 705 3466
Contact Person:	George Gallagher
Date Prepared:	October 30, 2021

Device Name and Classification

Trade Name:	DoubleCHEK
Model Number(s):	DC-1001
Classification Name:	Gastrointestinal Tubes with Enteral Specific Connectors (21 CFR 876.5980)
Product Code:	KNT
Class:	II

Predicate Device

Trade Name:	Kendall CO_2nfirm NOW^{TM} CO_2 Detector
Model Number(s):	777702
Classification Name:	Gastrointestinal Tubes with Enteral Specific Connectors (21 CFR 876.5980)
Product Code:	KNT
Class:	II
510(k) Number:	K042572

Device Description

The proposed device, DoubleCHEK DC-1001 is a hand-held, non-powered disposable device which consists of CO_2 and pH chambers ultrasonically welded to the device upper (top) and the reservoir interface. pH and CO_2 indicator papers are integrated into the design directly underneath the top so they are visible to the users next to the primary device label which contains the color scale.

There are three ports where accessories are intended to be connected to the device to enable use:

- The Syringe Port: A male ENFit connector designed per ISO 80369-3:2016.
- The NG Tube (NGT) Port: A female ENFit connector designed per ISO 80369-3:2016.
- The Reservoir Interface: A 22 mm bung style connector.

To use the proposed device, the user attaches the reservoir to the reservoir interface, the naso/orogastric tube to the NGT Port and the syringe to the Syringe Port. The user then pumps the syringe (withdraws the plunger) to aspirate either liquid (stomach contents) or gas (exhalation gas). The gaseous aspirate will traverse the sample pathway to the CO_2 indicator paper [5], where the presence or absence of CO_2 can be detected via a color change in the paper. The liquid aspirate will traverse through the sample pathway to the pH paper, which will indicate pH level via a color change in the paper.

Indications for Use

Intended Use:
DoubleCHEK is intended to indicate whether the tip of a naso/oro gastric tube is in an acidic or CO_2 environment during or after initial placement. The DoubleCHEK is NOT intended to confirm the location of the naso/oro gastric tube.

Indications for Use:

The DoubleCHEK is indicated for use with an initially placed or an in-situ naso/oro gatric tube. It is intended to indicate whether the tip of a naso/oro gastric tube is in an acidic or CO_2 environment during or after initial placement. It is NOT intended to confirm the location of the naso/oro gastric tube. The device is intended to be used by Health Care Professionals on all patients within a health care setting. The device is intended to be used with a single patient for up to 24 hours.

Product Comparison Summary

The proposed and predicate devices are substantially equivalent.

Criteria for Comparison	Proposed Device Compared to Predicate Device
Intended Use	
Indications	Similar and SE
Clinical Settings	Same
Target Population	Similar and SE
Design Characteristics	
Naso/orogastric Tube Connection	Similar and SE
Aspiration Device Connection	Similar and SE
Indicator Paper	Similar and SE
Materials	
Device	Different (unknown)
Performance	
Use/Human Factors	Same
Theory of Operation	Same
pH Detection	Different
CO_2 Detection	Same as predicate device
Fluid administration prevention	Different (predicate device does not have feature)
Risk Assessment	Different (unknown)
Safety	
Mechanical	Similar and SE
Electrical	Same – not electrical devices
Radiation	Same – not radiation emitting devices

Non-Clinical Performance Testing

Non-clinical performance testing was conducted to demonstrate that the proposed device, the DoubleCHEK DC-1001, is substantially equivalent to the predicate device and is safe and effective for its intended use.

The following tests were performed:

- Biocompatibility evaluation per ISO 1093-1
- ISO 80369-3:2016 Tests
    - Positive Pressure Liquid Leakage
    - Stress Cracking
    - Resistance to Separation from Axial Load
    - Resistance to Separation from Unscrewing
    - Resistance to Overriding
    - Disconnection by Unscrewing
- Packaging Visual Inspection
- IFU Visual Inspection
- Device Visual Inspection
- Pressure Profile
- pH Indicator Imprecision and Bias Studies
- CO_2 Indicator Imprecision and Bias Studies

- Device Working Life, including:
    - Repeated assessment of C02 indication performance
    - Repeated assessment of pH indication performance
    - Reset performance
    - Device Integrity

Clinical Performance Testing

Clinical performance testing was not required to demonstrate the performance of the DoubleCHEK DC-1001. The DoubleCHEK DC-1001 performance has been adequately demonstrated by the completion of non-clinical performance testing.

Animal Testing

Animal testing was not required to demonstrate the performance of the DoubleCHEK DC-1001. The DoubleCHEK DC-1001 performance has been adequately demonstrated by the completion of non-clinical performance testing.

Conclusion

The results of the non-clinical performance testing demonstrate that the DoubleCHEK DC-1001 is as safe and effective as the predicate device. Therefore, the proposed device is substantially equivalent to the predicate device.