DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 21, 2016

Century Pharmaceuticals, Inc.
Mr. Stephen Deardorff
Vice President
10377 Hague Road
Indianapolis, IN 46256

Re: K150208
Trade/Device Name: Dakin's Skin and Wound Cleanser
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 2, 2016
Received: June 8, 2016

Dear Mr. Deardorff:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150208

Device Name
Dakin's Skin and Wound Cleanser

Indications for Use *(Describe)*
Dakin's Skin and Wound Cleanser is intended for cleansing of acute, chronic and open wounds such as stage I-IV pressure ulcers, diabetic foot and leg ulcers, surgical wounds, first and second degree burns, and grafted and donor sites.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150208

Device Name
Dakin's Skin and Wound Cleanser

Indications for Use *(Describe)*
Dakin's Skin and Wound Cleanser is intended for cleansing of minor cuts, minor lacerations, minor abrasions and minor wounds, and for removal of foreign objects such as dirt and debris.

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.

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Century Pharmaceuticals, Inc.
10377 Hague Road
Indianapolis, IN 46256
Tel (317) 849-4210
Fax (317) 849-4263

Official Contact: Stephen Deardorff – Vice President

Proprietary or Trade Name: Dakin's Skin and Wound Cleanser

Common/Usual Name: Wound cleanser

Classification Name/Code: FRO - DRESSING, WOUND, DRUG

Device: Dakin's Skin and Wound Cleanser, Quarter Strength 0.125%

Predicate Device: Patrin Pharma, Inc. – Hy-Chlo Wound Solution – K113312

Device Description:
The Dakin's Skin and Wound Cleanser, Sodium Hypochlorite 0.125% is an aqueous, clear, colorless solution with mild chlorine odor, modified with sodium bicarbonate, used as a solution to cleanse and debride wounds. Sodium hypochlorite is used as a solution preservative, and sodium bicarbonate is used as a pH modifier.

Dakin's Skin and Wound Cleanser is packaged in amber HDPE (High Density PolyEthylene) bottles and induction sealed caps. A permanently affixed label, lot number and expiration date will be on each bottle of the Dakin's Skin and Wound Cleanser.

Indications for Use:

OTC: Dakin's Skin and Wound Cleanser is intended for cleansing of minor cuts, minor lacerations, minor abrasions and minor wounds, and for removal of foreign objects such as dirt and debris.

Professional Use: Dakin's Skin and Wound Cleanser is intended for cleansing of acute, chronic and open wounds such as stage I-IV pressure ulcers, diabetic foot and leg ulcers, surgical wounds, first and second degree burns, and grafted and donor sites.

Patient Population: Patients with acute or chronic wounds.

Environment of Use: Hospitals, nursing homes, wound clinics and pre and post hospitals

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Summary of substantial equivalence

	Predicate **Patrin Pharma – Hy-Chlo** **K113312**	**Proposed** **Dakin's Skin and Wound Cleanser,** **Quarter Strength 0.125%**
Indications for Use	**OTC:** Hy-chlo Wound Solution is intended for removal of foreign objects such as dirt, for cleansing of minor cuts, lacerations, abrasions and wounds. **Professional Use:** Hy-chlo Wound Solution is intended to be used under the supervision of healthcare professional in cleansing of acute, chronic and/or open wounds such as Stage I-IV pressure ulcers, diabetic foot and leg ulcers, surgical wounds, first and second degree burns and grafted and donor sites.	**OTC:** Dakin's Skin and Wound Cleanser is intended for cleansing of minor cuts, minor lacerations, minor abrasions and minor wounds, and for removal of foreign objects such as dirt and debris. **Professional Use:** Dakin's Skin and Wound Cleanser is intended for cleansing of acute, chronic and open wounds such as stage I-IV pressure ulcers, diabetic foot and leg ulcers, surgical wounds, first and second degree burns, and grafted and donor sites.
OTC Prescriptive	OTC Prescriptive (Professional use)	OTC Prescriptive (Professional use)
Environments of use	Attended healthcare setting such as acute and non-acute care hospitals, nursing homes, surgery centers, emergency rooms and wound clinics.	Hospitals, nursing homes, wound clinics and pre and post hospitals

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	Predicate **Patrin Pharma – Hy-Chlo** **K113312**	**Proposed** **Dakin's Skin and Wound Cleanser,** **Quarter Strength 0.125%**
Ingredients	Purified Water Sodium bicarbonate Sodium Hydroxide Sodium Hypochlorite concentration: 0.125% weight/volume	Purified Water Sodium bicarbonate Sodium Hydroxide Sodium Hypochlorite concentration: 0.125% weight/volume
Non-clinical Performance Biocompatibility	Tested as stated in 510(k) Summary	Cytotoxicity Sensitization Dermal Irritation
Preclinical Wound Healing Study in Yucatan miniature swine	Daily treatment did not inhibit the healing process when compared with untreated sites.	Daily treatment of the abraded site with either Dakin's Skin and Wound Cleanser or Predicate did not inhibit the healing process when compared with untreated sites.
Antimicrobial (preservative testing)	S. aureus, E.Coli, P. aeruginosa, C. albicans, S.aureus (MRSA), A. Brasiliensis, mold and yeast.	Multi-microbial challenge testing meets the criteria in the USP <51> Antimicrobial Effectiveness Testing
Contraindications and Warnings	***Warnings*:** ▪ For external use only ▪ Keep out of reach of children ▪ If swallowed, contact Poison Center or seek immediate medical attention ▪ If redness, irritation, swelling or pain appears or increases, contact doctor immediately ▪ Do not use if sensitive to chlorine	***Warnings*:** ▪ **For external use only** ▪ **Stop use and ask a doctor if** redness, irritation, swelling or pain persists or increases. ▪ **Do not use if** sensitive to any of the compounds ▪ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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The Dakin's Skin and Wound Cleanser, Quarter Strength 0.125% is viewed as substantially equivalent to the predicate device because:

Indications

- Identical to predicate – Patrin Pharma – Hy-Chlo - K113312

Formulation / Technology

- Similar formulation / technology used to predicate – Patrin Pharma – Hy-Chlo - K113312

Materials

- The materials in patient contact are identical to predicate device, Patrin Pharma – Hy-Chlo – K113312

Environment of Use

- Identical to predicate – Patrin Pharma– Hy-Chlo – K113312

Differences

- No significant differences between the proposed device and the predicate device, and do not introduce any new patient safety issues.