K060298

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MAR 2 9 2006

510(k) SUMMARY

Vocel
PILL PHONE Medication Reminder Software Device
510(k) Premarket Notification

Submitter

Vocel
13400 Sabre Springs Parkway
Suite 255
San Diego, CA 92128

Contact Person: Mr. Chris Nelson
Date Prepared: January 27, 2006

Name and Classification of Device

Trade or Proprietary Name:	PILL PHONE
Common Name:	medication reminder system
Classification Name:	daily assist device
Product Code :	unknown

Predicate Devices

The PILL PHONE is substantially equivalent to the ONCELLRX, the MEDPARTNER, and various medication reminder systems marketed by E-Pill, LLC.

Description of the PILL PHONE

The PILL PHONE software device will be sold to users of cell phones (or other communication devices) through their cell phone service. The software will have a feature to send out reminders to a cell phone owner of the dosing schedule that has been programmed into the phone, whether the dosing schedule is for the user, a child, or an elderly parent. The software will also enable the delivery of information about medications, such as indications for use, dosing, side effects, and even photographs of different pills. The PILL PHONE software is a Minor Level of Concern.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2006

Vocel
C/O Mr. Keith A. Barritt
Fish & Richardson, Professional Corporation
1425 K Street, N.W.
Suite 1100
Washington, DC 20005

Re: K060298
Trade/Device Name: Pill Phone
Regulation Number: 890.5050
Regulation Name: Daily activity assist device
Regulatory Class: I
Product Code: NXQ
Dated: February 3, 2006
Received: February 7, 2006

Dear Mr. Barritt:

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 (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.

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.

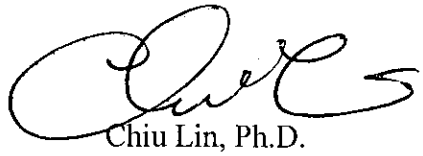
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Dental, Anesthesiology, General
Hospital, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K060298

Device Name: PILL PHONE

Indications For Use:

The PILL PHONE is a medication reminder and information system utilizing software that operates on a user's cell phone or other wireless device. The PILL PHONE will also have the ability to receive multiple question surveys from the PILL PHONE server.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

...ology, General Hospital,
...ical Dental Devices

K060298