EXHIBIT C

510(k) Summary

JUN 17 2011

SafetyMate, Inc.
1633 Monrovia Ave.
Costa Mesa, California 92627

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K110625.

Submitter's Identification:

Submitter's name:	SafetyMate, Inc.
Address:	1633 Monrovia Avenue Costa Mesa, California 92627
Phone:	949.722.1121
Fax:	949.764.1774
Name of contact person:	Sharon Cohen, Ph.D. Vice President sharon@safetymate.com
Phone:	949.722.1121
Date Summary Prepared:	June 15, 2011

2. **Name of the Device:**

Name of device:	SafetyMate, SM200 Series
Classification name:	Kit, first aid, talking
New Product Code:	OVR
Class:	1
Regulation Number:	878.4014
Definition:	The device provides verbal instructions pertaining to various first aid and common medical emergencies. The device does not contain any drug or supporting device that could be applied to the patient.

3. **Common or Usual Name:**

SafetyMate Talking First Aid

4. **Predicate Device Information:**

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

Reference #	Device Name	Applicant
Exempt	510(k) Exempt First Aid Kits Without Drugs	

5. Device Description:

SafetyMate® Talking First Aid, SM200 Series is a hand-held, interactive talking first aid guide for adult, child or infant emergencies. It includes eight themed first aid categories including CPR/Unconscious, Choking/Breathing, Allergic Reaction, Bleeding, Burns, Falls/Bone Injury, Poison/Bites/Stings, and Seizures. Besides providing guidance for what to do in case of an emergency, SafetyMate also highlights what not to do to prevent further injury. SafetyMate is designed to reinforce and remind users of the correct steps and procedures to provide established first aid care.

6. Intended Use:

SafetyMate® Talking First Aid, SM200 Series is an electronic device intended for use to provide verbal information from established sources to refresh how to handle common medical emergencies through utilization of button options, voice queries and prompts which remind the user of important points in the management of identified emergency situations for infant, child, and adult emergencies.

7. Comparison to Predicate Device:

Table #1

Subject Area	SafetyMate, SM200 Series	First Aid Kit Without Drug Predicates (510(k) Exempt)	Similar or Different
Product Code	OVR (*the Agency created a new product code to better accommodate / define the subject device)	OHO	Different
Product Classification	Class I	Class I	Similar
Classification Name	Kit, talking, first aid	Non-Resorbable gauze /sponge for external Use	Different
Proprietary Name	SafetyMate, SM200 Series	First Aid Kit Without Drug	
Intended Use	Talking First Aid assistance	Supplies to be used	Similar
Indications for Use	Intended for use as an adjunct to first aid / responder training and information sources through utilization of	Intended for use as an adjunct to first aid offering the user an external means of absorbing body fluids in the management of emergency	Different

	voice queries and prompts which remind the user of important points in the management of identified emergency situations.	situation	
Intended Population	Infant, child and adult	Infant, child and adult	Similar
Technological features – Mode of Operation	Electronic talking first aid device. User selects one of eight first aid categories. Voice queries prompt user to select age-appropriate instructions.	No technological features	Different
Design	Electronic audio aid in performing CPR and other first aid activities. Audio beeps proper CPR cadence with voice prompt for breaths. Software controlled. Has eight user selection buttons which guide the user through the proper first aid steps with audio instructions. Voice queries prompt user to select age category.	Porous material used to soak up liquid/bodily fluids. Not software controlled.	Different
Materials:	Plastic body with eight button selections. Battery powered.	Porous material. Not battery powered.	Different
Performance	First aid assistant device with eight major first aid areas.	First aid assistant materials.	Different
Specifications	Hand held device	Hand held product(s)	Different
Mechanical Safety	None	None	Similar
Chemical Safety	N/A	N/A	Similar
Anatomical Sites	N/A	Wherever bodily fluid is gushing	Different
Human Factors	Designed for ease of use	Designed for ease of use	Similar
Energy Used/Delivered	Electrical none delivered	Electrical none delivered	Similar

Compatibility with the environment and other devices	Standard luer connections to administration devices	N/A	Different
Where used	Home or office	Home or office	Similar
Standards met	See Section I – CDRH Premarket Review Submission Cover Sheet	Unknown	
Electrical Safety	See Exhibit J	Unknown	
Thermal safety	N/A	N/A	
Radiation safety	N/A	N/A	

8. **Discussion of Non-Clinical Tests Performed:**

Table #2

SM202	Standard	Title
SM202	EN 55014-1 EN 55022	Electromagnetic compatibility – Requirements for household appliances and similar apparatus – Part 1 Emissions
SM202	EN 55014-2 EN 61000-4-2	Electromagnetic compatibility – Requirements for household appliances and similar apparatus – Part 2 Immunity
SM202	FCC Part 15 Section 15.109	Radiated Emission

9. **Discussion of Clinical Tests Performed:**

Clinical usability and human factors studies were conducted to assess if SafetyMate Talking First Aid Device impairs appropriateness of care and/or speed to treat. Conclusions indicated that overall, no significant delays in treatment were noted. While there were a few instances in which changes to the protocols needed to be made to address points of confusion, either over word choice or clarity of instructions, those changes have been implemented and the issues have been answered.

10. **Conclusions:**

Based on the design, technology, performance, functional testing, and intended use, the SafetyMate, SM200 series is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. Usability studies indicate that 100% of the users were able to use the device correctly without any prompting from the observer. The human factors study addressed two questions: first, whether the use of an audio prompting device (in this case, a SafetyMate Talking First Aid device), in a simulated first aid emergency situation, caused a delay in treatment when compared to the same situation without a prompting device; and second, whether the use of a prompting device lead the subjects to render inappropriate care, in a simulated first aid emergency situation. While there were a few instances in which changes to the protocols needed to be made, those changes have been implemented and the issues have been answered.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Sharon Cohen Ph.D
Vice President
SafetyMate, Incorporated
1633 Monrovia Avenue
Costa Mesa, California 92627

JUN 17 2011

Re: K110625
Trade/Device Name: SafetyMate® Talking First Aid, SM200 Series
Regulation Number: 21 CFR 878.4014
Regulation Name: Nonresorbable Gauze/Sponge for External use
Regulatory Class: I
Product Code: OVR
Dated: May 10, 2011
Received: May12, 2011

Dear Dr. Cohen:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit E

Indications for Use

510(k) Number (if known): K110625

Device Name: SafetyMate® Talking First Aid, SM200 Series

Indications For Use:

SafetyMate® Talking First Aid, SM200 Series is an electronic device intended for use to provide verbal information from established sources to refresh how to handle common medical emergencies through utilization of button options, voice queries and prompts which remind the user of important points in the management of identified emergency situations for infant, child, and adult emergencies.

Prescription Use _____ **OR** **Over-The Counter Use** X
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

NAT 6/1/2011 Weiling Gu for RZC. 6/1/2011

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110625