

Panel Recommendation

1 GENERIC TYPE OF DEVICE

Diagnostic Alcohol Monitoring System

2 ADVISORY PANEL

Clinical and Toxicology

3 IS DEVICE AN IMPLANT (21 CFR 860.3)?

Yes No

4 INDICATIONS FOR USE IN THE DEVICE'S LABELING

The SCRAM™ Bracelet is a device intended to measure alcohol in the human body through transdermal measurement. Measurements obtained by this device are intended to detect and monitor alcohol consumption and may be used to detect alcohol intoxication. The SCRAM™ Bracelet is a non-invasive instrument or system intended for use in the diagnosis of a condition or the state of health

5 IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE

General The minimal risks that have been noted with the SCRAM device include the following:

- Significant discomfort, due to improper sizing of the SCRAM Bracelet;
- Bouncing of the SCRAM Bracelet on the ankle while exercising;
- Minor bruising on certain participants;
- Minor delays at airport security (5 -7 minutes);
- Transdermal alcohol concentration curves have been shown to be broader and have lower peaks than the breath alcohol concentration curve;
- SCRAM showed discriminative validity as a quantitative measure of alcohol consumption;
- Data may get spiky, probably due to water accumulating in the sensor;
- If water is present the sensor may lose the ability to detect ethanol or have delayed sensitivity;
- Paced drinking with food may not trigger an "alert;"
- Detection algorithm is good, but not perfect;
- Modem does not work with mobile telephones;
- A few landlines had trouble dialing out; and
- Preliminary data has shown that sweat or cold will alter the detectable response.

6 RECOMMENDED ADVISORY PANEL CLASSIFICATION AND PRIORITY

Classification Class I Non-Reserved Priority (Class II or III Only) _____

7 IF DEVICE IS AN IMPLANT, OR IS LIFE-SUSTAINING OR LIFE-SUPPORTING AND HAS BEEN CLASSIFIED IN A CATEGORY OTHER THAN CLASS III, EXPLAIN FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA

Not Applicable

8 SUMMARY OF INFORMATION, INCLUDING CLINICAL EXPERIENCE OR JUDGMENT, UPON WHICH CLASSIFICATION RECOMMENDATION IS BASED

In 1982, the Clinical Toxicology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of breath-alcohol test systems :

1. Identification: A breath-alcohol test system is a device used to measure alcohol in the human breath. The device utilizes qualitative gas chromatography to distinguish between various alcohols (i.e., ethanol, methanol, isopropanol, and acetone). Measurements obtained by this device are used in the diagnosis of alcohol intoxication.
2. Recommended classification: Class I (general controls).
3. Summary of reasons for recommendation: The Panel recommends that breath-alcohol test systems be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.
4. Summary of data on which recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.
5. Risks to health: None identified.
6. FDA Determination: FDA agreed with the Panel recommendation and proposed that breath alcohol test systems be classified into class I (general controls). The FDA believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

The Panel particularly relied upon clinical experience and judgment when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments makes clear that the term "data" has a special meaning in section 513(c)(2)(A) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in that section, "data" refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or judgments of experts. (FDA has determined that clinical experience and judgment is valid scientific evidence for classifying certain devices.)

9 IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE (e.g., special labeling, banning, or prescription use)

10 IF DEVICE IS RECOMMENDED FOR CLASS I, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM

Justification / Comments

- a Registration / Device Listing _____
- b Premarket Notification Please see attached petition _____
- c Records and Reports _____
- d Good Manufacturing Practice _____

11 IF DEVICE IS RECOMMENDED FOR CLASS II, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM PREMARKET NOTIFICATION

- a Exempt
- b Not Exempt

Justifications/Comments

12 EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES (*Components*) OR DEVICE MATERIALS (*Parts and Accessories*)

“Evaluation of Precision Performance of Clinical Chemistry Devices;” Approved Guideline (1999)
National Committee for Clinical Laboratory Standards (NCCLS)

13 COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs (HFZ-215)
1350 Piccard Drive
Rockville, MD 20850

OMB STATEMENT

Public reporting burden for this collection of information is estimated to average 1-2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to

Department of Health and Human Services
Food and Drug Administration, (HFZ-215)
2094 Gaither Road
Rockville, MD 20850

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INSTRUCTIONS FOR SUPPLEMENTAL DATA SHEET

1. The Supplemental Data Sheet should be prepared in conjunction with the General Device Questionnaire. The preparer should refer to Title 21 Part 860 of the Code of Federal Regulations for classification / reclassification definitions and procedures.
2. The Supplemental Data Sheet is designed to provide the device description, intended use, the risks of the device, the recommended class and the scientific support for the class and proposed level of controls.
3. The information requested by questions 1 through 8 must be provided for all devices
4. Question 9 can be answered by referring to question 11 of the General Device Questionnaire.
5. Question 10 refers only to devices recommended for class I, and is a recommendation for exemptions from the General Controls listed.
6. Question 11 refers only to devices recommended for Class II.
7. Question 12 requests the listing of any existing standards for the device being classified. The standards to be listed could be standards drafted by professional groups, standards groups or manufacturers.
8. Send this completed form and the appropriate questionnaire to the address indicated in item 13

EXHIBIT B