

APR 27 1995

K942633

510(k) SUMMARY

ORAL-B INTERDENTAL WOODSTICKS WITH FLUORIDE

This 510(k) Summary of Safety and Effectiveness is submitted in accordance with the requirements of SMDA 1990

Oral-B Interdental Woodsticks With Fluoride are substantially equivalent to Oral-B Interdental Woodsticks and to Oral-B Dental Floss With Fluoride. Each woodstick contains 0.1mg of sodium fluoride which is recognized as a safe and effective anticaries agent. However, the primary mode of action of Oral-B Interdental Woodsticks With Fluoride is to mechanically remove plaque and food particles from between the teeth and to stimulate the gums. Oral-B Interdental Woodsticks have been clinically proven to significantly reduce gingival bleeding and remove bacterial plaque.

Sharon Snyder
Director of Regulatory Affairs
Oral-B Laboratories
June 2, 1994



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 27 1995

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sharon Synder
Director, Regulatory Affairs
Oral-B Laboratories
One Lagoon Drive
Redwood City, California 94065-1561

Re: K942633
Trade Name: Oral-B Interdental Woodsticks with
Fluoride
Regulatory Class: I
Product Code: JET
Dated: June 2, 1994
Received: June 3, 1994

Dear Ms. Snyder:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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.

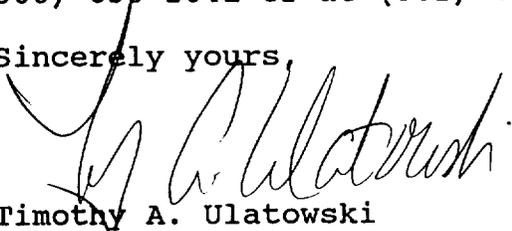
Please be advised of our concerns regarding the proprietary name for your device which includes the word "fluoride". Although no specific claims with regard to fluoride content are made in the labeling, fluoride is a commonly recognized active ingredient in dental products associated with anticaries activity. Therefore, the name of the device, Oral-B Interdental Woodsticks with Fluoride, implies that the fluoride ingredient will prevent caries. The Food and Drug Administration (FDA) is reevaluating the regulatory status of over-the-counter dental devices containing fluoride, including those for which no specific claims with regard to fluoride content are made in the labeling. You may receive further correspondence regarding this reevaluation.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Timothy A. Ulatowski
Acting Director
Pilot Division
Office of Device Evaluation
Center for Devices and
Radiological Health



510(K) ROUTE SLIP

510(k) NUMBER K942633 PANEL DE DIVISION DGRD BRANCH DEDB

TRADE NAME ORAL-B INTERDENTAL WOODSTICKS WITH FLUORIDE

COMMON NAME TOOTHPICK

PRODUCT CODE _____

APPLICANT ORAL-B LABORATORIES

SHORT NAME ORALBLABO

CONTACT SHARON SNYDER

DIVISION _____

ADDRESS ONE LAGOON DRIVE

REDWOOD CITY, CA 94065

PHONE NO. (415) 598-5000

FAX NO. (____) ____-____

MANUFACTURER ORAL-B LABORATORIES

REGISTRATION NO. 2936806

DATE ON SUBMISSION 02-JUN-94

DATE DUE TO 510(K) STAFF 17-AUG-94

DATE RECEIVED IN ODE 03-JUN-94

DATE DECISION DUE 01-SEP-94

DECISION _____

DECISION DATE _____

B



Memorandum

Date 4/25/95

From REVIEWER(S) - NAME(S) Myra Browne

Subject 510(k) NOTIFICATION R942633

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes No

This 510(k) contains: (check appropriate box(es))

- A 510(k) summary of safety and effectiveness, or
- A 510(k) statement that safety and effectiveness information will be made available
- The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

76 JET 872.6 ~~650~~ 650 CEI

Additional Product Code(s) w/Panel (optional):

REVIEW:

Louis Skovira
(BRANCH CHIEF)

DEPB
(BRANCH CODE)

4/27/95
(DATE)

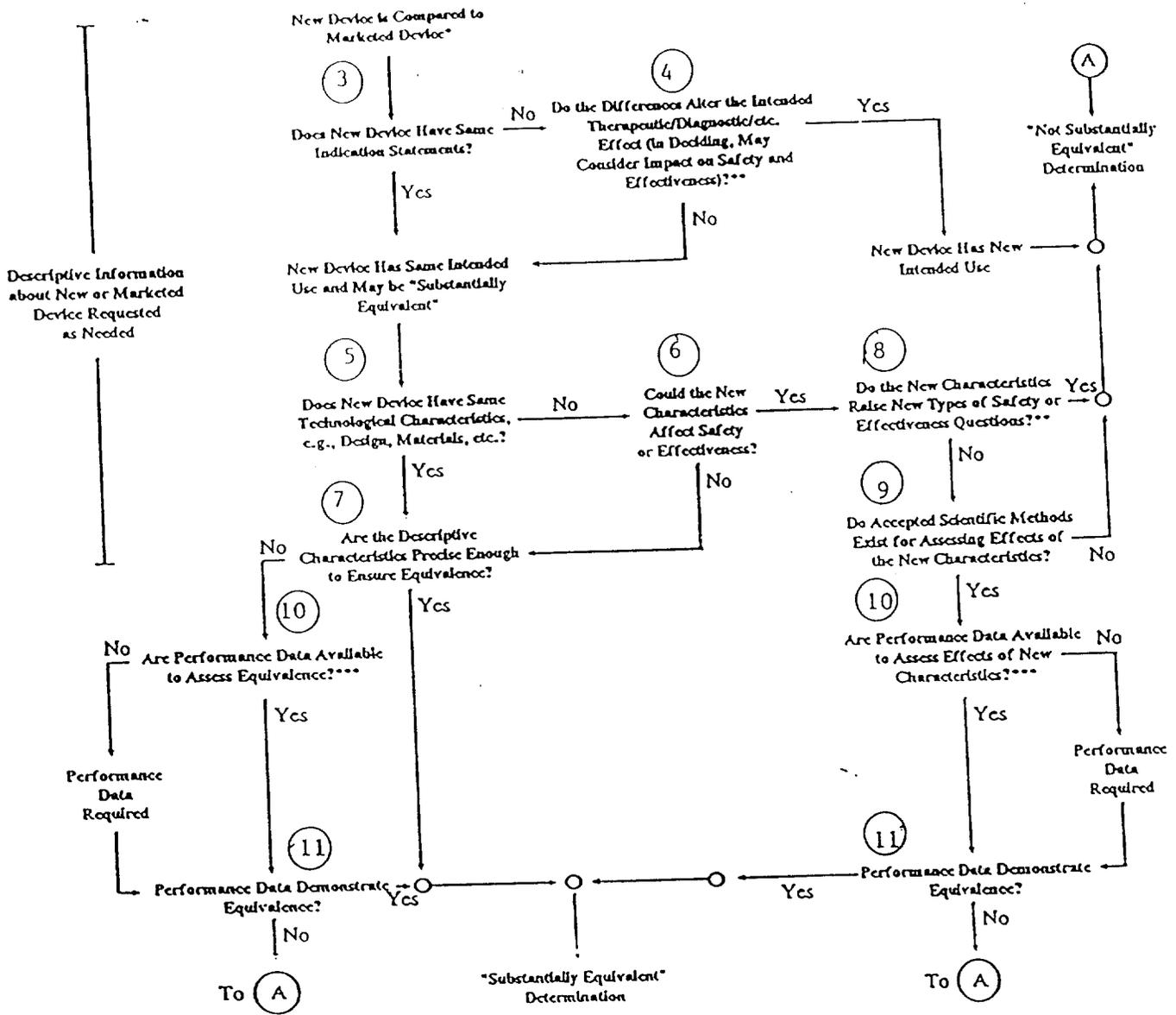
FINAL REVIEW:

[Signature]
(DIVISION DIRECTOR)

4/27/95
(DATE)

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510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



- * 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

April 27, 1995

FROM: Acting Director, PILOT
SUBJECT: Pending Dental Flosses with Fluoride
TO: Record

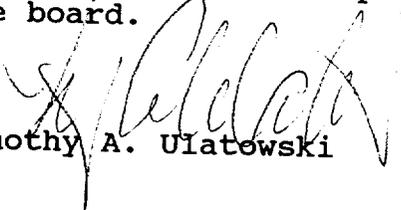
The Dental Branch has had a number of 510(k)s pending for dental flosses with fluoride. What has hung them is a regulatory issue.

There are pending recision letters for marketed flosses with fluorides. CDER and CDRH decided that clinical data are needed to demonstrate safety and effectiveness of the fluoride in the flosses. The anticaries claim for the fluoride was not addressed in the 510(k)s for the marketed devices. No clinical data was submitted in those 510(k)s. So, it was decided to rescind them.

Applicants for pending 510(k)s were going to be asked to supply clinical data once the rescissions issued.

In a 1-on-1 with Dr. Alpert on April 20, 1995 I pointed out to her that the rescissions were taking longer to get out than anticipated. I noted that it was perpetuating an unfair advantage for those on the market over those pending. Since the products were low risk I asked if we should SE the 510(k)s and deal with the clinical data issue separately. The downside is that it may mean more rescissions in the future.

We decided to SE the products and ask for clinical data across the board.


Timothy A. Ulatowski

PILOT Evaluation Staff Checklist
for Premarket Notifications (510(k)s)

| Device Trade Name: <u>Intuitive Surgical sticks w/ 7 lowide</u> K# <u>94263B</u> | | |
|--|-------------------------------------|-------------------------------------|
| Submitter Name: <u>CIA/B Laboratories</u> | | |
| Date Received: <u>JUN 20 1994</u> | | |
| 90 Day Due Date: <u>15 Sep 94</u> | | |
| Review Tier (circle one): <u>(1)</u> 2 3 | | |
| Question | Yes | No |
| A. Is the product a device? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| B. Is the device exempt from 510(k)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| C. Expedited Review Status: Requested by sponsor, | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| or identified by PILOT Staff | <input type="checkbox"/> | <input type="checkbox"/> |
| Granted by Pilot Staff? | <input type="checkbox"/> | <input type="checkbox"/> |
| D. Has this device been the subject of a previous NSE decision? | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data? | <input type="checkbox"/> | <input type="checkbox"/> |
| E. Has the sponsor been the subject of an integrity investigation? | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| If yes, has the ODE Integrity Officer given permission to proceed with the review? | <input type="checkbox"/> | <input type="checkbox"/> |

Administrative Reviewer Signature: _____

Date: 6/27/94

Benita Heard / Mary J. Jensen

Supervisory Signature: _____

Date: _____

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NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: to remove plaque and food particles from between the teeth; and to massage and stimulate the gums
2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

SUMMARY: Oral-B Interdental Woodsticks with fluoride are interdental toothpicks made of Norwegian Birchwood and coated with sodium fluoride. These sticks are made in Norway for Oral-B. Each wood stick contains .10 mg (as opposed to .15 mg per 18 inches of dental floss by Oral-B)

Oral-B Interdental Woodsticks are substantially equivalent to other picks for oral hygiene such as Oral-B Interdental Woodsticks without fluoride. They are equivalent in design, composition, safety and effectiveness.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. EXPLAIN WHY NOT A DEVICE: _____

2. EXPLAIN WHY NOT SUBJECT TO 510(k): _____

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION: _____

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE: _____

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS: _____

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS: _____

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7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH: _____

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW: _____

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED: _____

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED: _____

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT: _____

ATTACH ADDITIONAL SUPPORTING INFORMATION

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Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

June 08, 1994

ORAL-B LABORATORIES
ONE LAGOON DRIVE
REDWOOD CITY, CA 94065
ATTN: SHARON SNYDER

510(k) Number: K942633
Received: 03-JUN-94
Product: ORAL-B
INTERDENTAL
WOODSTICKS WITH
FLUORIDE

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. Although the traditional timeframes for reviewing 510(k)s has been 90 days, it is now taking longer. These increasing response times have been caused by many factors, including a sharp increase in ODE's workload and increasingly complex device submissions. During 1992, we received about 1,500 more total submissions than we did the preceding year. We are troubled by these increases in response times and are making every effort to regain predictability in the timing of 510(k) reviews. Due to the increase in response times, CDRH has established a 510(k) Status Reporting System through which submitters may receive a status report on their 510(k) submissions(s) as follows:

- o Beginning 90 days after ODE receives your 510(k) submission, you may begin requesting status information. Submit requests via fax (301-443-8818) or via mail to:
 - 510(k) Status Coordinator
 - Division of Small Manufacturers Assistance (DSMA) (HFZ-220)
 - Center for Devices and Radiological Health, FDA
 - 5600 Fishers Lane
 - Rockville, Maryland 20857 USABecause of staff limitations, we cannot answer telephone status requests.
- o 510(k) status requests should include:
 - (1) submitter's name and mailing address;
 - (2) requester's name, affiliation with the 510(k) submitter, mailing address, fax number (if applicable), telephone number, and signature; and



- (3) 510(k) information, including product name, 510(k) number, date logged in by ODE (as identified in acknowledgment letter from ODE), and name of contact person identified on firm's 510(k) submission.

Enclosed is a suggested format that you may use to ensure that you include all of the required information.

- o Within three working days after DSMA receives a submitter's status request, DSMA will send the submitter a fax or letter that includes:
 - (1) the branch to which the 510(k) has been assigned;
 - (2) the last action, and date of that action, that CDRH has taken regarding the 510(k), e.g., logging in an amendment, preparing a decision letter; and
 - (3) the position of the 510(k) in the reviewer's queue.

We request that 510(k) submitters make status inquiries no more than every four weeks. We do not have the resources to respond more frequently.

The SMDA also requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages 510(k) submitters to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that their device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The

description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

As of March 9, 1993, FDA has implemented the Good Manufacturing Practice(GMP) Pre-Clearance Inspection Program for all class III devices that are being reviewed under the premarket notification program. A letter of substantial equivalence cannot be sent until the finished device manufacturing site(s) and sterilization sites(s) as appropriate, have been identified and FDA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820).

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/ Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health



PREMARKET NOTIFICATION (510(k)) STATUS REQUEST

TO: 510(k) Status Coordinator
Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health, FDA
5600 Fishers Lane
Rockville, MD 20857
USA
Fax Number: (301) 443-8818

Please provide the status of the 510(k) identified below. Please send the information to the requester identified in section B by (check one):

fax
 mail

A. Sponsor Information:

- 1. Name of 510(k) sponsor: _____
- 2. Sponsor's mailing address: _____

B. Requester information:

- 1. Request name: _____
- 2. Requester affiliation with sponsor: _____
- 3. Requester mailing address: _____

- 4. Request fax number (if applicable): _____
- 5. Requester telephone number: _____

C. 510(k) information:

- 1. Product name: _____
- 2. 510(k) number: _____
- 3. Date logged in by Office of Device Evaluation (ODE) (as identified in acknowledgment letter from ODE): _____

Name of contact person identified on firm's 510(k) submission: _____

.....
I certify that the above information is accurate and truthful to the best of my knowledge.

Requester signature 