DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JUL 24 1990

Ms. Pauline W. Bonderman
Analytical Control Systems, Inc.
9001 Technology Drive
Suite A
Fishers, Indiana 46038

Re: K902457
Abnormal Glycohemoglobin
Control
Dated: May 9, 1990
Received: June 4, 1990
Regulatory Class: II

Dear Ms. Bonderman:

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments 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 anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. 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,

Thomas M. Tsakeris

Thomas M. Tsakeris
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date . JUL 16 1990

From REVIEWER(S) - NAME(S) Chris Brauer

Subject 510(k) NOTIFICATION K902509

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:

The submitter requests under 21 CFR §807.95:

X No Confidentiality

_____ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

HIS / 884.5300 / Class II

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

_____

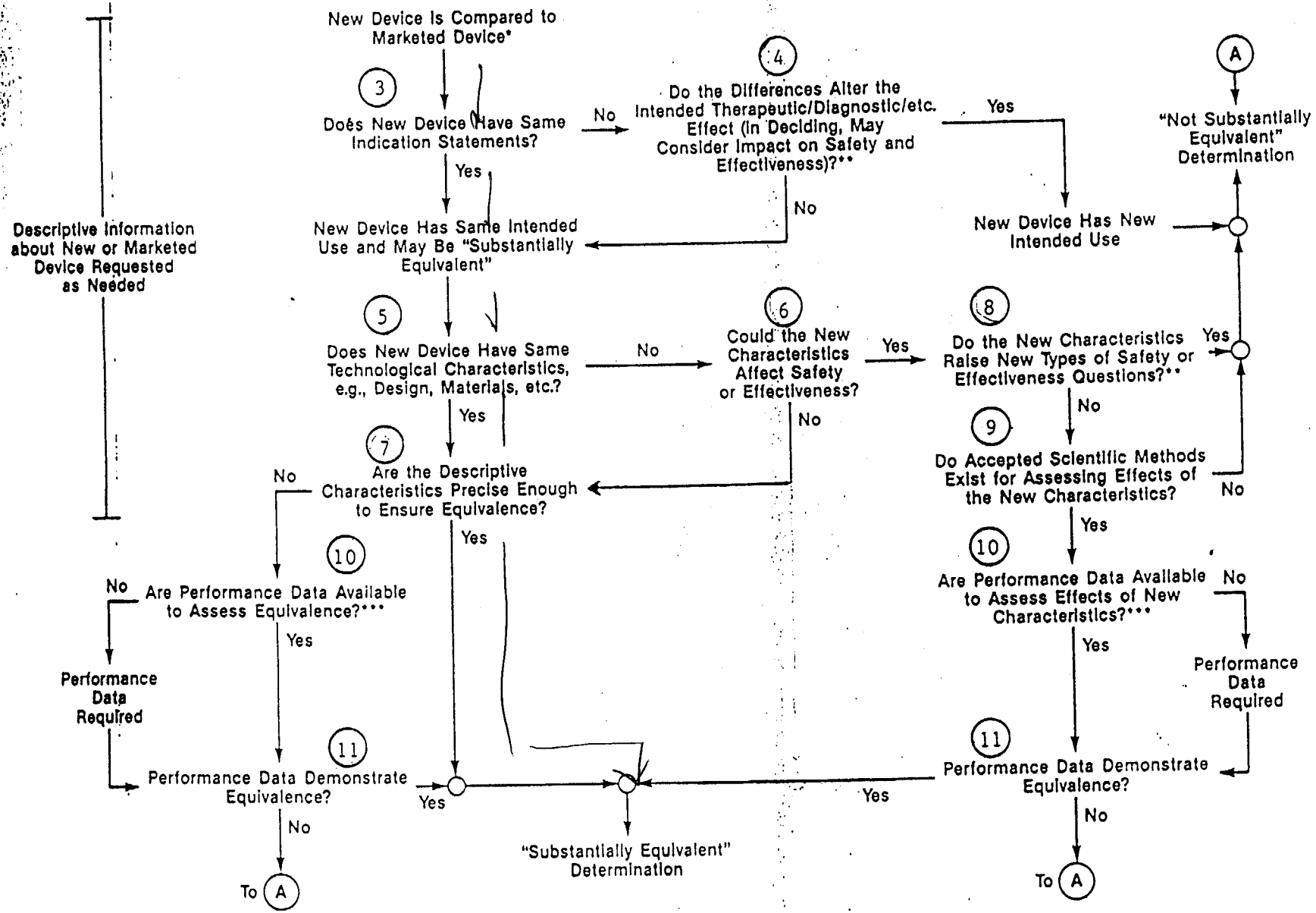
REVIEW: Ray G. Kammula 7/17/90
(BRANCH CHIEF) (DATE)

FINAL REVIEW: David A. Seymour 7/23/90
(DIVISION DIRECTOR) (DATE)

X

X2

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"

** 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.

K 902509 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: Chris Brauer DIVISION/BRANCH: DOED / OB-GYN

TRADE NAME: Sasson Ribbed Condoms COMMON NAME: Condom

PRODUCT TO WHICH COMPARED: Trojan Condoms - Shelf-life
(510(k) NUMBER IF KNOWN)

		YES	NO	
1.	IS PRODUCT A DEVICE?	✓		- IF NO STOP
2.	DEVICE SUBJECT TO 510(k)?	✓		- IF NO STOP
3.	SAME INDICATION STATEMENT?	✓		- IF YES GO TO 5
(4.)	DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP - NE
5.	SAME TECHNOLOGICAL CHARACTERISTICS?	✓		- IF YES GO TO 7
(6.)	COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			- IF YES GO TO 8
7.	DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	✓		- IF NO GO TO 10 - IF YES STOP - SE
(8.)	NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			- IF YES STOP - NE
9.	ACCEPTED SCIENTIFIC METHODS EXIST?			- IF NO STOP - NE
10.	PERFORMANCE DATA AVAILABLE?			- IF NO REQUEST DATA
(11.)	DATA DEMONSTRATE EQUIVALENCE?			

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: see attached review

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: see attach Review

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:_____

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

Review of Premarket Notification
Obstetrics-Gynecology Devices Branch
Document Control Number: K902509
Login Date: 06/05/90
90 Day Due Date: 09/03/90
Device: Saxon Ribbed™ Condoms
Manufacturer: Safetex Corporation
16101 Continental Boulevard
Colonial Heights, Virginia 23834

Description of Device and Intended Use:

Saxon Ribbed™ Condoms are Type II (textured surface) lubricated (silicone) latex condoms which have been in commercial distribution since 1975. The condoms are intended for contraceptive and prophylactic purposes.

Review Summary:

The sponsor has submitted this premarket notification (510(k)) to add a tentative expiration date to the labeling of these condoms. The submission has been forwarded as suggested by FDA in the October 1989 "General Guidance for Modifying Condom Labeling to Include Shelf Life".

The sponsor has conducted accelerated aging on the latex condoms according to ASTM Test Method D 573 and requests a 4 year tentative expiration date.

The sponsor has also initiated real time testing procedures according to ASTM Test Methods D 3492-83 and D 3492-89 to confirm the tentative date. The sponsor has also provided adequate information to assure that a statistically valid sample size is being used in the testing procedures.

Recommendation:

I recommend that the sponsor can add a tentative expiration date of 4 years to this device.

Christine Brauer
Christine Brauer

Date: July 16, 1990

Branch, Chief

Date: 7/16/90
Concur ✓ /
Do Not Concur/ /

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

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 8, 1990

SAFETEX CORP.
ATTN: RONALD L. DAVIS
16101 CONTINENTAL BLVD.
COLONIAL HEIGHTS, VA 23834

D.C. Number : K902509
Received : 06-05-90
90th Day : 09-03-90
Product : SAXON RIBBED CONDOMS

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug, and Cosmetic Act for the above referenced device has been received and assigned an unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, 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) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

SAFETEX CORPORATION

K902509

FDA-CDRH-GDE

JUN 0 5 1990

DOCUMENT MAIL CENTER

May 30, 1990

Dear Mr. Kammula:

I previously submitted 510 Ks for all of our Safetex product line but accidently ommitted the 510K for the Saxon Ribbed. We have received approval on all other products and, therefore, I feel confident that this submission will also be approved.

Thank you.

Sincerely,

Ronald L Davis

Ronald L. Davis
Quality Control Manager

11

Headquarters & Plant:
16101 Continental Blvd.
Colonial Heights, VA 23834
Tel: (804) 520-8341
Fax: (804) 520-7040

Sales Office:
1100 Valley Brook Avenue
Lyndhurst, NJ 07071
Tel: (201) 460-7331
Fax: (201) 460-8819
(800) 426-2092

May 30, 1990

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HF2-401)
1390 Piccard Drive
Rockville, Maryland 20850

Premarket Notification (510K) Submission

Dear Dr. Kammula:

I am submitting this Premarket Notification (510K), following the suggested format for labeling modifications to identify condom shelf life.

1. Applicant: Safetex Corporation
   16101 Continental Blvd.
   Colonial Heights, VA
   United States 23834
   Registration Number - 1122329

2. Contact Person: Ronald L. Davis
   Quality Control Manager
   804-520-8341

3. Manufacturer: Same as applicant

4. Product Identification:
   a. Trade Name: Saxon Ribbed
   b. Pre-Amendment Device-Year Introduced: 1975

5. Packaging System:
   a. Description - Printed and laminated condom pouch stocks

   b. Material - Reverse printed 250 HB Cellophane (3 colors) 7.2# polyethylene - .003" foil - 18.5# polyethylene extrusion.

   c. Roll Stock - 4-7/16" x 2-1/2" c/o x 3" ID core x 9" maximum OD

   d. The tested condoms are packaged on horizontal and vertical continuous motion form, fill and heat seal

machines.

6. Accelerated Aging Test Method:
   a. A.S.T.M. Method: D 573 Test Method for rubber - deterioration in an air oven.

   b. Shelf Life: 4 years

7. Real Time Testing Procedures:
   a. Storage conditions: Condom samples are stored in an enclosed metal cabinet at 70°F ± 2°F located in the Quality Control Department Laboratory.

   b. Sample size and test interval: There are 103 condom samples taken per lot to include A.S.T.M. D 3492-83 and A.S.T.M. D 3492-89 requirements on a six month routine basis.

   c. Specific testing methods: All of the testing methods follow the guidelines specified by A.S.T.M. D 3492-83 and -89.

   d. Real time shelf life: Due to the fact that a tentative expiration date is requested, Safetex will notify the FDA with confirmation data on real time shelf life.

Sincerely,

Ronald L Davis

Ronald L. Davis
Quality Control Manager

RLD/sge

Document Separator

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date July 25, 1990

Returned TO DOED
Needs Confirmation Letter Typed.

From Jessica S. Lewis, Clerk-Typist (CDRH, ODE, DMC) HFZ-401

Subject Premarket Notification Number(s) K902509 J 7/30/90

To Division Director OB

The attached information has been received by 510(k) Document Mail Center (DMC), on the above referenced 510(k) file(s). Since a final decision has been rendered, the record is officially closed.

Please review the document(s) and return to DMC directed to my attention, with one of the statements checked below. Feel free to note any additional comments below. If there are any questions, please contact me on 427-1027. Thank you for your cooperation.

✓ Information does not change status of 510(k); no other action required by DMC; please file. The Division should prepare a confirmation letter - example attached.

_____ Additional information requires a new 510(k); please process.

COMMENTS: No letter needed

This information should be returned by Aug. 13, 1990.

Reviewed by: [signature]

Panel: _____ Date: 8/2/90

Attachment

BEST COPY AVAILABLE

1

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Re: Device Name
Dated:
Received:

Dear _____:

We have reviewed the information dated _____, regarding the 510(k) notification (K_____) previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

If you have any questions regarding the contents of this letter, please contact _____ at (301) 427-____.

Sincerely yours,

Division Director
Division of _____
Office of Device Evaluation
Center for Devices and
Radiological Health

SAFETEX CORPORATION

Headquarters & Plant:
16101 Continental Blvd.
Colonial Heights, VA 23834
Tel: (804) 520-8341
Fax: (804) 520-7040

Sales Office:
1100 Valley Brook Avenue
Lyndhurst, NJ 07071
Tel: (201) 460-7331
Fax: (201) 460-8819
(800) 426-2092

July 17, 1990

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HF2-401)
1390 Piccard Drive
Rockville, Maryland 20850

Premarket Notification (510K) Submission
D.C. Number: K902509

Dear Mr. Kammula:

I am submitting some additional information per the request of the Food and Drug Administration on the Saxon brand ribbed condom.

1) This condom is [redacted]

2) The average lot size per day is [redacted]

3) Test Interval and Sample Size: [redacted]

I hope that this information satisfactorily meets your request.

Sincerely,

Ronald L. Davis
Quality Control Manager

RLD/sge

Document Separator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JUL 24 1990

Mr. Ronald L. Davis
Quality Control Manager
Safetex Corporation
16101 Continental Boulevard
Colonial Heights, Virigina 23834

Re: K902509
Condom Shelf Life (4 years)
Saxon Ribbed Condoms (tentative)
Dated: May 30, 1990
Received: June 5, 1990
Regulatory Class: II
21 CFR 884.5300

Dear Mr. Davis:

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) 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 895. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments 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 anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. 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,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of OB-GYN, ENT,
and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health