Bioteque America, Inc.
340 East Maple Avenue
Langhorne, PA 19047

9/7/93

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

RE: K920633

Dear Marjorie,

We have received your letter dated 8/27/93 concerning K920633 and we would like to re-inform your office that Bioteque America, Inc. has changed its office address to:

Bioteque America, Inc.
340 E. Maple Avenue - Suite 102
Langhorne, PA 19047

We have also changed the product name from:

Nichols Vaginal Stent

to:

Pessary Flexible Silicone Nichols

Would you please correct your records to reflect these changes.
Thank you very much.

Sincerely,

Denis Dorsey, President
Bioteque America, Inc.

Tel (215) 750-8071
(800) 889-9008
Fax (215) 750-8073

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV -8 1995

Mr. James D. Dorsey
Vice President/Regulatory Affairs
Bioteque America, Inc.
340 East Maple Avenue, Suite 102
Langhorne, Pennsylvania 19047

Re: K920633
Nichols Counsellor (Obturator Type)
Vaginal Stent
Dated: August 29, 1995
Received: September 1, 1995
Regulatory Class: II
21 CFR 884.3900/Procode: 85 KXP

Dear Mr. Dorsey:

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.

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, the 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 may have 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-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose, and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(K) ROUTE SLIP

510(k) NUMBER K920633 PANEL OB DIVISION DRAER BRANCH OGDB

TRADE NAME PESSARY FLEXIBLE SILICONE NICHOLS

COMMON NAME

PRODUCT CODE

APPLICANT BIOTEQUE AMERICA, INC.
SHORT NAME BIOTAMER
CONTACT DENNIS DORSEY
DIVISION
ADDRESS 340 E. MAPLE AVENUE
SUITE 102
LANGHORNE, PA 19047
PHONE NO. (215) 750-8071 FAX NO. (___) ___-____

MANUFACTURER BIOTEQUE AMERICA, INC. REGISTRATION NO. 2529577

DATE ON SUBMISSION 27-JAN-92 DATE DUE TO 510(K) STAFF 27-SEP-94

DATE RECEIVED IN ODE 12-FEB-92 DATE DECISION DUE 12-OCT-94

DECISION __ DECISION DATE

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	29-MAY-92	29-MAY-92	27-AUG-92	14-AUG-92	
S002	15-JUL-93	24-AUG-93	07-NOV-93	22-NOV-93	09-MAR-94
S003	28-MAR-94	04-APR-94	18-JUN-94	03-JUL-94	20-JUN-94
S004	16-JUN-94	14-JUL-94	27-SEP-94	12-OCT-94	01-DEC-94
S005	31-JAN-95	03-FEB-95	19-APR-95	04-MAY-95	04-MAY-95
S006	31-MAY-95	31-MAY-95	14-AUG-95	29-AUG-95	08-JUN-95
S007	08-JUN-95	12-JUN-95	26-AUG-95	10-SEP-95	29-JUN-95
S008	29-AUG-95	01-SEP-95	15-NOV-95	30-NOV-95	

CORRESPONDENCE	SENT	DUE BACK	
C001	29-APR-92	29-MAY-92	HOLD LETTER
C002	14-AUG-92	13-SEP-92	HOLD LETTER
C003	09-MAR-94	08-APR-94	HOLD LETTER
C004	20-JUN-94	20-JUL-94	HOLD LETTER
C005	01-DEC-94	04-FEB-95	HOLD LETTER
C006	04-MAY-95	03-JUN-95	HOLD LETTER
C007	08-JUN-95	08-JUL-95	HOLD LETTER

SE 7

510(K) ROUTE SLIP

C008	29-JUN-95	30-SEP-95	HOLD LETTER		

OTHER SUBMISSIONS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
ADD-TO-FILE	03-AUG-94	12-AUG-94	11-OCT-94		
ADD-TO-FILE	21-SEP-94	21-SEP-94	20-NOV-94		
ADD-TO-FILE	27-JUL-95	02-AUG-95	01-OCT-95		

B

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

From REVIEWER(S) - NAME(S) Mridulika Virmani

Subject 510(k) NUMBER K920633/S8

To THE RECORD -- It is my recommendation that the subject 510(k) Notification:

☒ Is substantially equivalent to marketed devices.

☐ Requires premarket approval. NOT substantially equivalent to marketed devices.

☐ Requires more data.

☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance? ☐ YES ☐ NO

Is this device subject to the Tracking Regulation? ☐ YES ☐ NO

Was clinical data necessary to support the review of this 510(k)? ☒ YES ☐ NO

This 510(k) contains: Truthful and Accurate Statement ☒ Requested ☐ Enclosed
(required for originals received 3-14-95 and after) N/A

☐ A 510(k) summary OR ☒ A 510(k) statement

☐ 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 with panel and class: 85 KXP Class II 21 CFR 884.3900

Additional Product Code(s) with panel (optional): 85 HDX, HFK

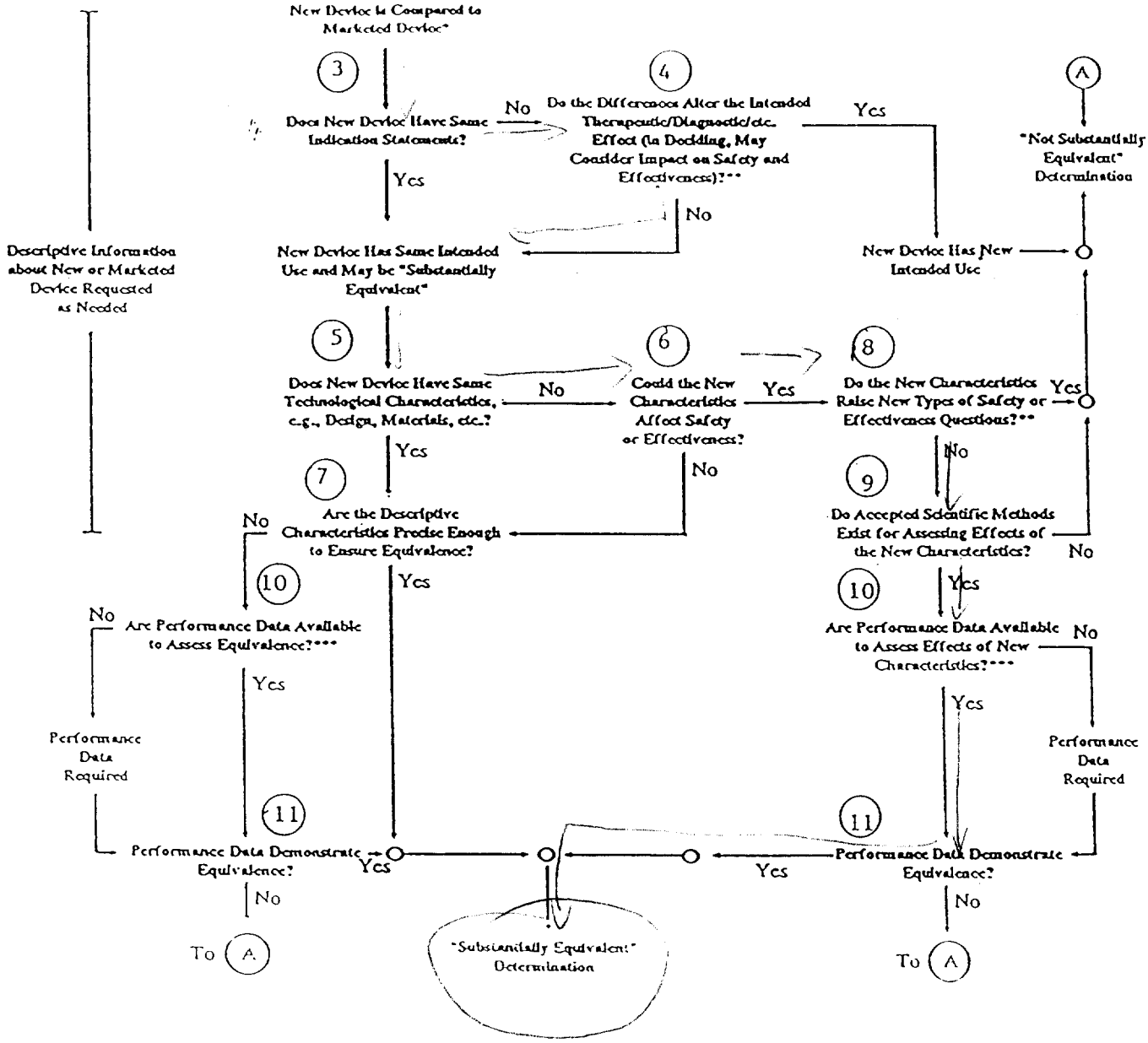
REVIEW: Colin M Pollard (BRANCH CHIEF) OGDB (BRANCH CODE) 11/7/95 (DATE) FMP

FINAL REVIEW: R Fallin / for LYin (DIVISION DIRECTOR) 11/7/95 (DATE)

Revised 3/8/95

4

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.

OBGD

K920633

Reviewer: *Mridulika Virmani, Ph.D.*
Chemist

Division/Branch: DRAERD/ADOU/OGDB
(HFZ-470)

Proprietary Trade Name: Formerly: Pessary Flexible Silicon Nichols
Changed To: NICHOLS COUNSELLOR (VAGINAL STENT)

Common Name: Obturator Type Vaginal Stent

Product to which compared: Counsellor Type Vaginal Stent (V. Mueller Co.)

Applicant: Bioteque America, Inc.
340 E. Maple Ave., Suite 102
Langhorne, PA 19047

Contact: Mr. Denis Dorsey
Phone: 215-750-8071

DEVICE DESCRIPTION

1. *Intended Use:*

This device is an intravaginal obturator, intended to support the vaginal vault. The device is used to support or distend the vaginal canal. This device can be used following the construction of a neovagina or following a vaginoplasty to enlarge a small vagina.

The device is removed, cleaned , and re-inserted by the patient from time to time, as per physician instructions. The device is not provided sterile or required to be sterile, but is intended for use only by a single patient, and cleaning periodically is important.

2. *Physical Description:*

	YES	NO
• 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 single use?	___	✓
• Is the device home use?	✓	___
• Is the device for prescription?	✓	___
• Does the device contain a drug or biological product as a component?	___	✓
• Is this device a kit?	___	✓

Provide a brief overview of the device, its design, principle of operation, and functional/performance characteristics.

Initially company has identified two predicate devices for this Pessary Flexible Silicone Nichols one is Milex's Gellhorn Pessary, and other is the Counsellor mold manufactured by the V. Mueller. The Gellhorn pessary is quite different in shape, size and indication of use than the Counsellor mold. The only similarity in Gellhorn pessary and Bioteque device is that both are made of silicone and fit intravaginally. The subject device is quite similar to Counsellor mold in shape, size and configuration, but the intended use are quite different as mentioned in the submission. The Counsellor mold is used as a stent to maintain the vagina in a reasonable open state and retard scarring while healing from vaginal plastic procedures and the subject device is used to reduce the genital prolapse. Company has withdrawn the device as Pessary, in this additional information submition dated, May 31, 1995 this device is intended only as an obturator.

A figure of predicate device is shown in a catalog, the original Mueller's product called the Counsellor is out of business since 1980. The predicate device was made of polyethylene. It was soft, and flexible. The subject device is made of silicone and resembles to predicate in shape and size. The Bioteque device is referred as intravaginal obturator/pessary.

The Bioteque Nichols vaginal obturator is elongated ovoid-shaped and comes in three sizes. Dimensional specifications are given as follows:

	Size 1 (small)	Size 2 (medium)	Size 3 (large)
Length	116.75 mm	125.50 mm	133.75 mm
Outer Diameter	30.75 mm	33.50 mm	41.70 mm
Inner Hollow tube	13.75 mm	14.75 mm	15.75 mm

The component material is medical grade silicone from NuSil MED-4840 is a two part silicone elastomer. The manufacturing is compression molding process. In this process the material is placed into a heated cavity and pressurized after a curing cycle, the parts are automatically ejected from the molds. The final product is of smooth surface with a A43 shore flexibility. No additional cleaning or mold releasing agents are used in this manufacturing process.

REVIEW ANALYSIS

SE comparison

The gellhorn pessary identified and compared in the submission as predicate is quite different in shape ,size and configuration than that of the subject device. This predicate is withdrawn by the company.

In this modified version of submission Company intends to use the V.Mueller's Counsellor Vaginal Mold, a hollow molded polyethylene, vented at either end, with a flat indentation on either side. Diameter, 1 3/9", and overall length 4 1/2". This device is used after vaginal surgery to distant the vaginal canal during the post-operative healing process to prevent unwanted contraction of the scar. The

vaginal stent is fitted and inserted by the physician and remains in place for up to several days. This Counsellor mold is similar to the bioteque's Nichols Counsellor in shape, size and design.

Sponsor has provided the supporting documentation and new indication of use (similar to Counsellor's indication for use) for the subject device.

Materials

Material used for this device is silicone supplied by Nusil. This material is equivalent to Dow Corning Silastic Q7-4840. Company has provided a MAf# 682 for this new material. I have examined this Master File and this material MED-4840 is equivalent to Dow-Corning's Q7-4840.

Manufacturing Process

The Bioteque device is compression molded at temperature and pressures consistent with the recommendations of the supplier. There are no additional chemicals or additives as mold releasing agent etc. used in the manufacturing process.

Toxicity

The sponsor has provided appropriate biocompatibility information in the MAF #682.

Packing

Each device will be packaged in a poly bag. A complete set of physician and patient instructions will be included with each device.

Labelling

The insertion and removal instructions are provided for the physician and patient. The cleaning instructions are also provided for the patients. The patient follow up instructions are provided. Fitting diagrams, contraindication, and adverse effects are included. Company has included a statement to the effect that they will include vaginal stent all along in the patient and physcian labeling along with Nichols Councellor.

Provide an overview of the review principles and findings that were used to support the reviewer recommendation.

For the review of this device and its labeling I have consulted Dr. Williams, several times. His reviews are attached at several places throughout the document. This document is here for such a long time, because of either lack of data or inconsistencies in data submission by the sponsor. Finally this submission is cleared as a NICHOLS COUNSELLOR VAGINAL STENT only. The latest labeling sent by the company received on September 29, 1995 have been shared with Dr. Williams and his concurrence is attached.

8

Substantial Equivalence (SE) Decision Making Documentation

		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 YES, STOP -> SE
8.	NEW TYPES OF SAFETY AND EFFECTIVENESS QUESTIONS	—	✓	IF YES, STOP -> NSE
9.	ACCEPTED SCIENTIFIC METHODS EXIST	✓**	—	IF NO, STOP -> NSE
10.	PERFORMANCE DATA AVAILABLE	✓	—	IF NO, REQUEST DATA
11.	DATA DEMONSTRATE EQUIVALENCE	✓	—	

* 4,5 and 6 In the initial submission company has provided two predicate devices with different indications.

** In final submission company used only one indication for use claim, using the appropriate predicate device.

9

REVIEWER RECOMMENDATION

Substantially Equivalent to vaginal stent.

ProCode: 85 KXP
Class: II
CFR #: 21 CFR §884.3900

Mridulika Virmani 11/3/95
Mridulika Virmani, Ph.D. Date

Colin M. Pollard 11/7/95
Colin M. Pollard Date
Chief, Ob/Gyn Devices Branch

/✓/ Concur
/ / Do Not Concur

Comments:

10

Bioteque America Inc.

Medical Products
Design & Development
Prototypes to Production

FAX MESSAGE

TO: Mridulika Virmani, Ph.D. FDA
FROM: Denis Dorsey Bioteque America, Inc.
DATE: 11/7/95

RE: K920633/E 2-pages including this page

As per our telephone conversation of 11/7/95, I am submitting the following addition to the Product Labeling-Physician/Patient instructions.

Please be advised that all instructional data or information concerning K920633/E will now include the words VAGINAL STENT as per your instructions.

Sincerely,

Denis Dorsey, President
Bioteque America, Inc.

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

Product Labeling - Physician/Patient

DISTRIBUTED BY:
BIO-AM™
Bioteque America, Inc.
340 East Maple Avenue
Suite 102
Langhorne, PA. 19047
Tel. (215) 750-8071
Fax (215) 750-8073

Bioteque America, Inc.

The Nichols Counsellor
(OBTURATOR-TYPE VAGINAL-STENT)

The Flexible Silicone Nichols Counsellor (obturator-type vaginal-stent) is available in three sizes.

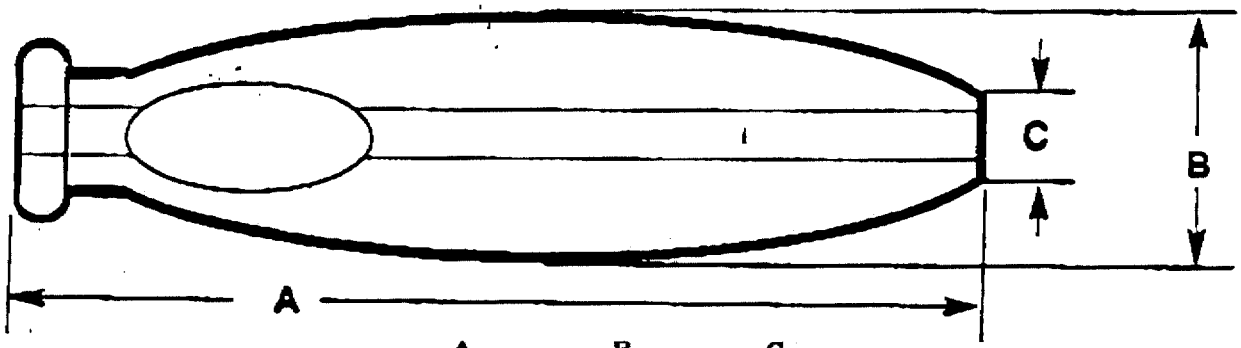
For single patient use only.

PRODUCT #: S116.75 (small), M125.50 (medium), L133.75 (large)

CAUTION:
Federal law (USA) restricts the sale of this device to or on the order of a physician.

INDICATIONS:
To support or distend the vaginal canal.

CONTRAINDICATIONS:
Vaginal counsellors are contraindicated in acute genital tract infections or in the presence of pelvic infections or lacerations and in noncomplient patients.



	A	B	C
SMALL	116.75 mm	30.75 mm	13.75 mm
MEDIUM	125.50 mm	33.60 mm	14.75 mm
LARGE	133.75 mm	41.70 mm	16.75 mm

PATENT PENDING

10

To: Mridu Virmani, Ph.D.
From: Eugene W. Williams, Jr., M.D.
Subject: K920633 Biotek's Vaginal "Counselor"
Date: September 27, 1995

As per your request, I have reviewed the September 20, 1995 faxed response to FDA's September 19, 1995 response to an earlier letter to Biotek. My comments are as follows:

(b) (4)

[redacted]

If the sponsor can make these changes, the submission should be clinically satisfactory.

Eugene W. Williams, Jr., M.D.
Medical Officer

13

Bioteque America Inc.

Medical Products
Design & Development
Prototypes to Production

FAX MESSAGE

TO: Mridulika Virmani, Ph.D. FDA
FROM: Denis Dorsey Bioteque America, Inc.
DATE: 9/29/95

RE: K920633/E Instructions (7-pages including this cover letter)

As per your instructions of 9/27/95, I have re-written our product literature including Product Labeling - Physician/Patient, Physician Instructions, Fitting Diagrams - Physician, Fitting Diagrams and Instructions - Patient and Patient Instructions - Adverse Effects. I sincerely hope this meets with your approval and we can conclude our submission concerning the Nichols Counsellor. All corrected versions have been sent in duplicate to the Document Mail Center.

For your information, David H. Nichols, MD, the innovator of the Counsellor, called me late yesterday (9/27/95) and informed me that the Nichols Counsellor can be used during the menstrual cycle. His colleague was in error when he told me the Counsellor should be removed during the menstrual cycle. Dr. Nichols reminded me that the Counsellor has a drainage hole from knob end to blunt end and during the menstrual period, the Counsellor should be removed every day and cleaned. Therefore, according to his wishes and your concerns, it is mentioned in the section titled "Fitting Diagrams and Instructions - Patient".

Sincerely,

Denis Dorsey
Bioteque America, Inc.

The 9/30/95 fax has shown the clinical changes that El suggested. Clinically

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

Product Labeling - Physician/Patient

DISTRIBUTED BY:
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Tel. (215) 750-8071
Fax (215) 750-8073

Bioteque America, Inc.

The Nichols Counsellor (OBTURATOR-TYPE)

The Flexible Silicone Nichols Counsellor (obturator-type) is available in three sizes.

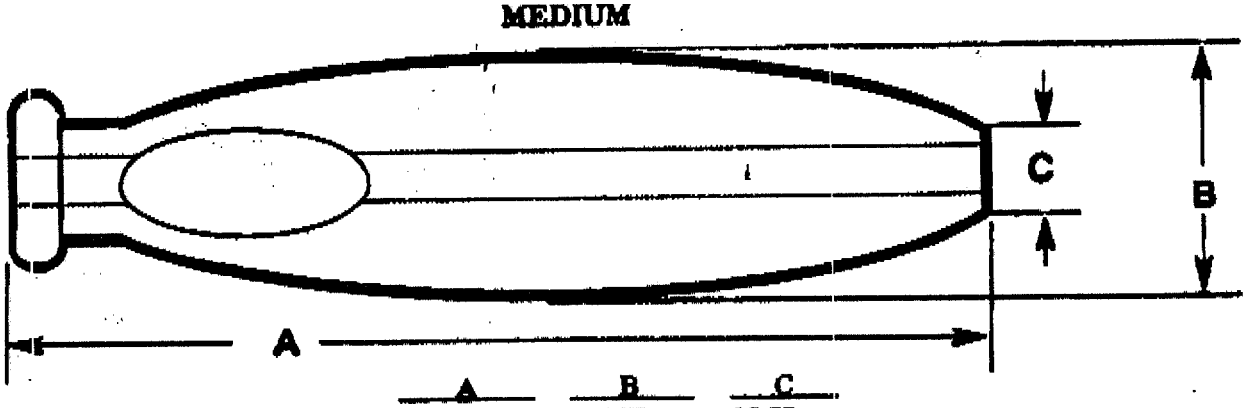
For single patient use only.

PRODUCT #: S116.75 (small), M125.50 (medium), L133.75 (large)

CAUTION:
Federal law (USA) restricts the sale of this device to or on the order of a physician.

INDICATIONS:
To support or distend the vaginal canal.

CONTRAINDICATIONS:
Vaginal counsellors are contraindicated in acute genital tract infections or in the presence of pelvic infections or lacerations and in noncompliant patients.



	A	B	C
SMALL	116.75 mm	30.75 mm	13.75 mm
MEDIUM	125.50 mm	33.50 mm	14.75 mm
LARGE	133.75 mm	41.70 mm	15.75 mm

PATENT PENDING

Physician Instructions

Promotional Material

Flexible Silicone
Nichols Counsellor
(obturator-type)

(photograph)

For Single Patient Use Only

CAUTION:

Federal law (USA) restricts the sale of this device to or on the order of a physician.

INDICATIONS:

To support or distend the vaginal canal.

CONTRAINDICATIONS:

Vaginal Counsellors are contraindicated in acute genital tract infections or in the presence of pelvic infections or lacerations and in noncomplient patients. The Counsellor should be removed prior to performing any x-ray, ultrasound, or MRI procedure.

DIRECTIONS FOR USE:

Fitting requires a trial of sizes to determine the proper Counsellor size.

#1. Perform a normal pelvic examination prior to the introduction or fitting of a Counsellor. The size selection is more of less trial and error however, a pelvic exam helps in determining the selection of the appropriate size.

#2. The Nichols Counsellor should be inserted base (the end opposite the removal stem) first into the introdus. When properly inserted, the stem should be in the downward position. Note that the flexibility of the Nichols Counsellor simplifies the insertion and removal.

#3. Once in place, the Counsellor should not dislodge by either standing, sitting, squatting or bearing down and it should not be uncomfortable for the patient during these normal routine activities.

Note: The Nichols Counsellor should be large enough to do its designed function while not causing any undue pressure or discomfort.

TO REMOVE:

#1. To remove the Nichols Counsellor, gently pull the stem end (the knob) to bring the Counsellor to the introdus and within fingers grasp.

#2. Use the fingers to open the labia for easy removal.

#3. After removal, completely wash the Counsellor with a mild soap and warm water and thoroughly rinsed.

#4. After the patient has been fitted with a Counsellor, be sure that within 24 to 48 hours the patient returns for an office visit. After removal of the Counsellor, examine the vagina and ask the patient if there has been any evidence of discomfort, pressure, or sensitivity to the Counsellor. Also, determine if there has been any improvement in her personal symptoms and be sure that your patient is not allergic to the Counsellor..

Note: Instruct the patient to report any discomforts immediately.

#5. It is necessary to check the fit of the Counsellor to be sure of the correct size for continued patient comfort and relief.

#6. Schedule follow-up visits to fit the needs of the individual patient.

SUGGESTED PATIENT FOLLOW-UP:

#1. Have the patient report any discomfort immediately.

#2. After initial insertion, remember to return to your physician within 24 to 48 hours to be sure you are not allergic to the Counsellor.

#3. The patient should be instructed to remove the Counsellor every day or two for cleaning. The Counsellor should be completely washed with a mild soap and warm water and thoroughly rinsed.

#4. Remember to schedule follow-up visits to fit the needs of the patient. Patient visits can be gradually lengthened to one or two month intervals.

Sizes available: Small, Medium and Large

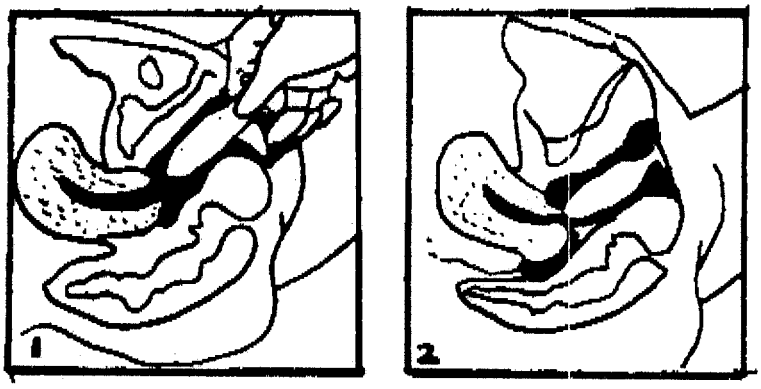
These instructions are the courtesy of David H. Nichols, MD

Fitting Diagrams - Physician

Instruct the patient to report any discomfort. The patient should return in twenty-four hours for the first examination. The patient should be instructed to remove the Counsellor every day or two for cleaning (wash with mild soap and warm water then thoroughly rinse before reinsertion). Have the patient return in three days for a second examination and then schedule monthly return visits.

During each visit the vagina should be checked for evidence of unnecessary pressure or allergic reactions. The patient should be questioned concerning douching, discharge, disturbance of bowel functions and urination.

1 When inserting the Counsellor, the pelvic muscles must be relaxed. With one hand spread the labia minora and with the other hand insert the blunt end of the well lubricated (use any water soluble gel) Counsellor into the vaginal cavity and gently apply inward pressure. Continue applying gentle pressure, pushing the Counsellor into the vagina until it stops and the knob end is comfortably within the vagina.



2 After the Counsellor is within the vagina vault, the Counsellor should be rotated so that a flattened surface (near the knob end) rests beneath the urethra. It is recommended that the patient wear a supportive sanitary napkin when the Counsellor is in place.

Fitting Diagrams and Instructions - Patient

Your physician has inserted a silicone vaginal support known as a Nichols Counsellor. When properly inserted it should be comfortable to the extent that whenever standing or reclining, you should be totally unaware of its presence.

The Counsellor may be used during your menstrual cycle. Please note that there is a drainage hole extending the full length of the Counsellor. During your menstrual cycle be sure to remove the Counsellor every day and wash with a mild soap and water and thoroughly rinse before reinsertion.

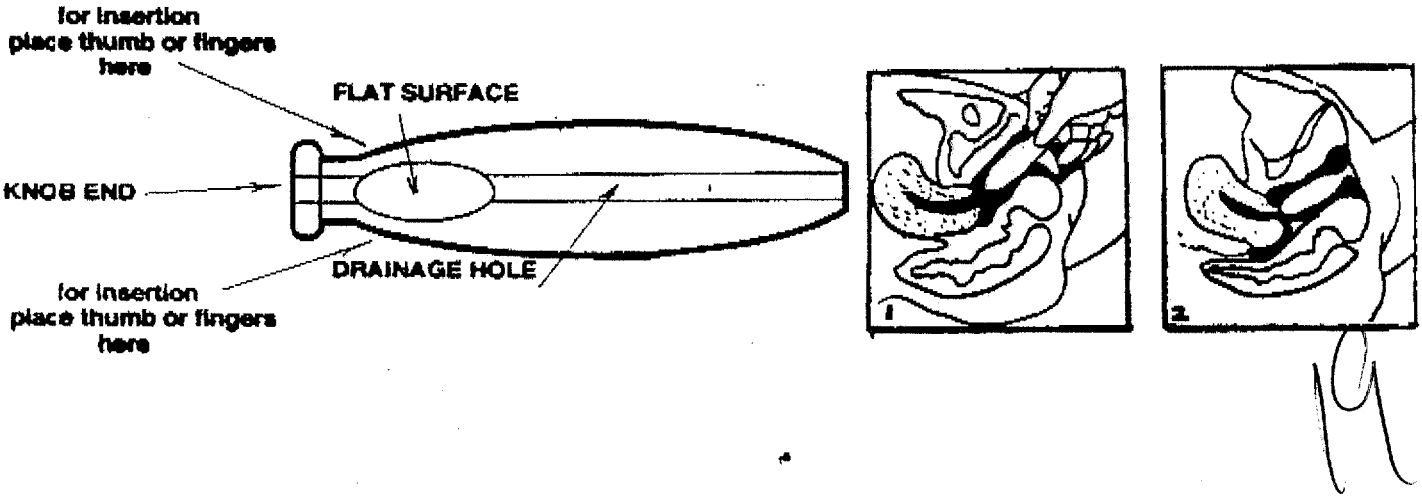
Your bowel and bladder habits should be unaffected by the Counsellor.

As a reminder, the Counsellor should be removed daily for cleaning using a mild soap and water and thoroughly rinse before reinsertion. The Counsellor is inserted and removed as diagrammed below.

1 When inserting the Counsellor, your pelvic muscles must be relaxed. With one hand spread the labia minora and with the other hand insert the blunt end of the well lubricated Counsellor into the vaginal cavity. You may use any water soluble gel to lubricate the Counsellor.

Before applying inward pressure, be sure that a flat surface of the Counsellor is clearly seen or felt and is in an upward position. You will notice that there are two flat surfaces on the Counsellor on opposite sides of the knob end. With one flat surface facing upward, grasp the Counsellor between your thumb and fingers keeping the flat surface in an upward position. Your physician should have demonstrated this maneuver to you. Now continue applying gentle inward pressure pushing the Counsellor into the vagina until it stops and the knob end is comfortably within the vagina. This will insure a flat surface will rest beneath the urethra.

2 After the Counsellor is within the vagina vault, a flattened surface (near the knob end) should be resting beneath the urethra, the external opening of the bladder. The following diagram indicates the proper insertion position. It is recommended that you wear a supportive sanitary napkin when the Counsellor is in place.



Patient Instructions - Adverse Effects

Recommended Follow-up for Nichols Counsellor Wearers

A. Immediately report any discomfort to your physician

B. Call your physician if the Counsellor should fall out.

C. Return for a follow-up examination within 24 hours.

D. Return for a second examination within three days.

E. Schedule follow-up examinations from one to two month intervals depending on your needs.

Adverse Effects

Report any of the following symptoms to your physician immediately.

- Any change in the color or consistency in your vaginal discharge.
- Any increase in the amount of vaginal discharge
- Any foul odor associated with your vaginal discharge.
- Any vaginal itching.

To: Mridu Virmani, Ph.D.
From: Eugene W. Williams, Jr., M.D.
Subject: K920633/S7
Date: June 23, 1995

In my April 18, 1995 review of this device, I posed several questions for the sponsor to answer. This response, dated June 8, 1995, has not answered those questions and has changed the intended use of the device to that which was submitted in the original 510K. That intended use was as a vaginal stent (obturator or "Counselor") which was placed into the vagina after vaginoplasty or construction of a neovagina. Although I do not find this device problematic for this purpose, the sponsor has submitted a comparative predicate device which is a picture in a supply catalogue. Although this may be deemed as adequate information, (b) (4) [redacted] . However, I have no definitive evidence to refute the use of the device will be other than what is stated as the intended use. It is reasonable to assume that labeling will control any off-label use that may be entertained by Biotek.

Eugene W. Williams, Jr., M.D.
Medical Officer

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

September 01, 1995

BIOTEQUE AMERICA, INC.
340 E. MAPLE AVENUE
SUITE 102
LANGHORNE, PA 19047
ATTN: DENNIS DORSEY

510(k) Number: K920633
Product: ~~PESSARY FLEXIBLE~~
~~SILI~~CONE NICHOLS
Nichols Counsellor
Obturator Type

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above 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.

The Safe Medical Devices Act of 1990, 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. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at 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

K920633/A4

Bioteque America Inc.

Medical Products
Design & Development
Prototypes to Production

MEMO

TO: Mridulika Virmani, Ph.D. FDA
FROM: Denis Dorsey Bioteque America, Inc.
DATE: 9/20/95

RE: K920633/E Instructions (7-pages including this cover letter)

As per your instructions of 9/27/95, I have re-written our product literature including Product Labeling - Physician/Patient, Physician Instructions, Fitting Diagrams - Physician, Fitting Diagrams and Instructions - Patient and Patient Instructions - Adverse Effects. I sincerely hope this meets with your approval and we can conclude our submission concerning the Nichols Counsellor.

For your information, David H. Nichols, MD, the innovator of the Counsellor, called me late yesterday (9/27/95) and informed me that the Nichols Counsellor can be used during the menstrual cycle. He reminded me that the Counsellor has a drainage hole from knob end to blunt end and during the menstrual period, the Counsellor should be removed every day and cleaned. Therefore, according to his wishes and your concerns, it is mentioned in the section titled "Fitting Diagrams and Instructions - Patient".

Sincerely,

Denis Dorsey
Bioteque America, Inc.

K920633/A4

Product Labeling - Physician/Patient

DISTRIBUTED BY:
BIO-AM™
Bioteque America, Inc.
340 East Maple Avenue
Suite 102
Langhorne, PA. 19047
Tel. (215) 750-8071
Fax (215) 750-8073

Bioteque America, Inc.

The Nichols Counsellor (OBTURATOR-TYPE)

The Flexible Silicone Nichols Counsellor (obturator-type) is available in three sizes.

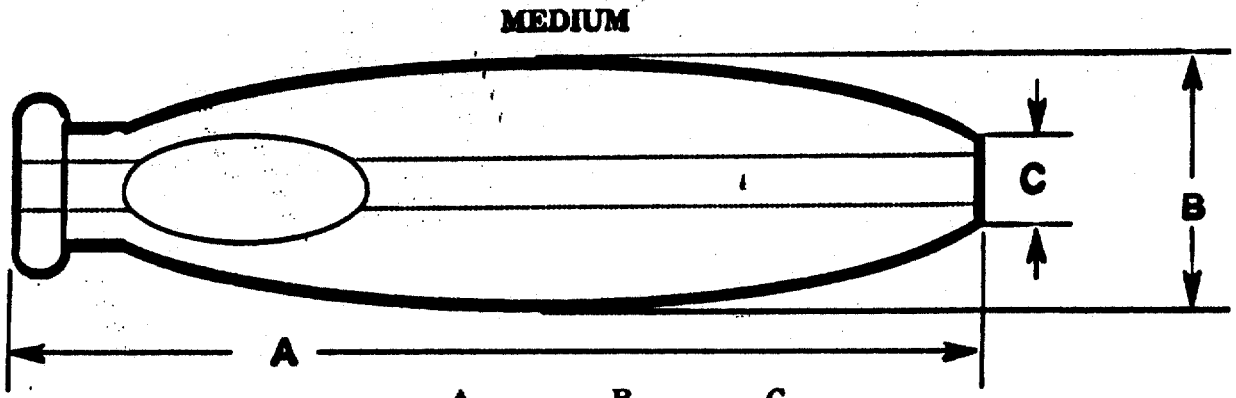
For single patient use only.

PRODUCT #: S116.75 (small), M125.50 (medium), L133.75 (large)

CAUTION:
Federal law (USA) restricts the sale of this device to or on the order of a physician.

INDICATIONS:
To support or distend the vaginal canal.

CONTRAINDICATIONS:
Vaginal counsellors are contraindicated in acute genital tract infections or in the presence of pelvic infections or lacerations and in noncomplient patients.



	A	B	C
SMALL	116.75 mm	30.75 mm	13.75 mm
MEDIUM	125.50 mm	33.50 mm	14.75 mm
LARGE	133.75 mm	41.70 mm	15.75 mm

PATENT PENDING

Physician Instructions

Promotional Material

Flexible Silicone
Nichols Counsellor
(obturator-type)

(photograph)

For Single Patient Use Only

CAUTION:

Federal law (USA) restricts the sale of this device to or on the order of a physician.

INDICATIONS:

To support or distend the vaginal canal.

CONTRAINDICATIONS:

Vaginal Counsellors are contraindicated in acute genital tract infections or in the presence of pelvic infections or lacerations and in noncomplient patients. The Counsellor should be removed prior to performing any x-ray, ultrasound, or MRI procedure.

DIRECTIONS FOR USE:

Fitting requires a trial of sizes to determine the proper Counsellor size.

#1. Perform a normal pelvic examination prior to the introduction or fitting of a Counsellor. The size selection is more of less trial and error however, a pelvic exam helps in determining the selection of the appropriate size.

#2. The Nichols Counsellor should be inserted base (the end opposite the removal stem) first into the introdus. When properly inserted, the stem should be in the downward position. Note that the flexibility of the Nichols Counsellor simplifies the insertion and removal.

#3. Once in place, the Counsellor should not dislodge by either standing, sitting, squatting or bearing down and it should not be uncomfortable for the patient during these normal routine activities.

Note: The Nichols Counsellor should be large enough to do its designed function while not causing any undue pressure or discomfort.

TO REMOVE:

#1. To remove the Nichols Counsellor, gently pull the stem end (the knob) to bring the Counsellor to the introdus and within fingers grasp.

#2. Use the fingers to open the labia for easy removal.

#3. After removal, completely wash the Counsellor with a mild soap and warm water and thoroughly rinsed.

#4. After the patient has been fitted with a Counsellor, be sure that within 24 to 48 hours the patient returns for an office visit. After removal of the Counsellor, examine the vagina and ask the patient if there has been any evidence of discomfort, pressure, or sensitivity to the Counsellor. Also, determine if there has been any improvement in her personal symptoms and be sure that your patient is not allergic to the Counsellor..

Note: Instruct the patient to report any discomforts immediately.

#5. It is necessary to check the fit of the Counsellor to be sure of the correct size for continued patient comfort and relief.

#6. Schedule follow-up visits to fit the needs of the individual patient.

SUGGESTED PATIENT FOLLOW-UP:

#1. Have the patient report any discomfort immediately.

#2. After initial insertion, remember to return to your physician within 24 to 48 hours to be sure you are not allergic to the Counsellor.

#3. The patient should be instructed to remove the Counsellor every day or two for cleaning. The Counsellor should be completely washed with a mild soap and warm water and thoroughly rinsed.

#4. Remember to schedule follow-up visits to fit the needs of the patient. Patient visits can be gradually lengthened to one or two month intervals.

Sizes available: Small, Medium and Large

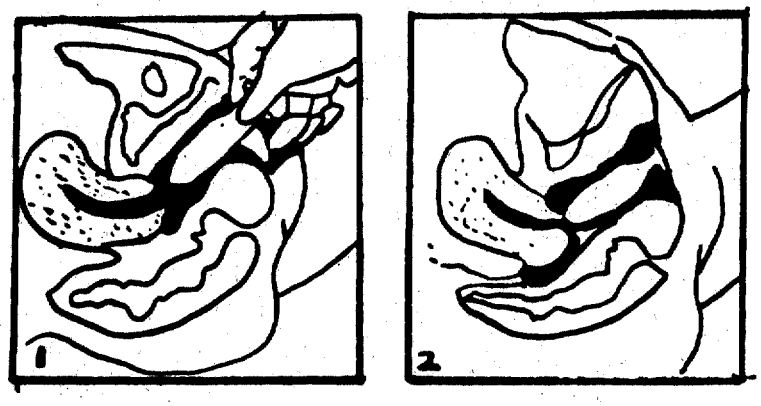
These instructions are the courtesy of David H. Nichols, MD

Fitting Diagrams - Physician

Instruct the patient to report any discomfort. The patient should return in twenty-four hours for the first examination. The patient should be instructed to remove the Counsellor every day or two for cleaning (wash with mild soap and warm water then thoroughly rinse before reinsertion). Have the patient return in three days for a second examination and then schedule monthly return visits.

During each visit the vagina should be checked for evidence of unnecessary pressure or allergic reactions. The patient should be questioned concerning douching, discharge, disturbance of bowel functions and urination.

1 When inserting the Counsellor, the pelvic muscles must be relaxed. With one hand spread the labia minora and with the other hand insert the blunt end of the well lubricated (use any water soluble gel) Counsellor into the vaginal cavity and gently apply inward pressure. Continue applying gentle pressure, pushing the Counsellor into the vagina until it stops and the knob end is comfortably within the vagina.



2 After the Counsellor is within the vagina vault, the Counsellor should be rotated so that a flattened surface (near the knob end) rests beneath the urethra. It is recommended that the patient wear a supportive sanitary napkin when the Counsellor is in place.

Fitting Diagrams and Instructions - Patient

Your physician has inserted a silicone vaginal support known as a Nichols Counsellor. When properly inserted it should be comfortable to the extent that whenever standing or reclining, you should be totally unaware of its presence.

The Counsellor may be used during your menstrual cycle. Please note that there is a drainage hole extending the full length of the Counsellor. During your menstrual cycle be sure to remove the Counsellor every day and wash with a mild soap and water and thoroughly rinse before reinsertion.

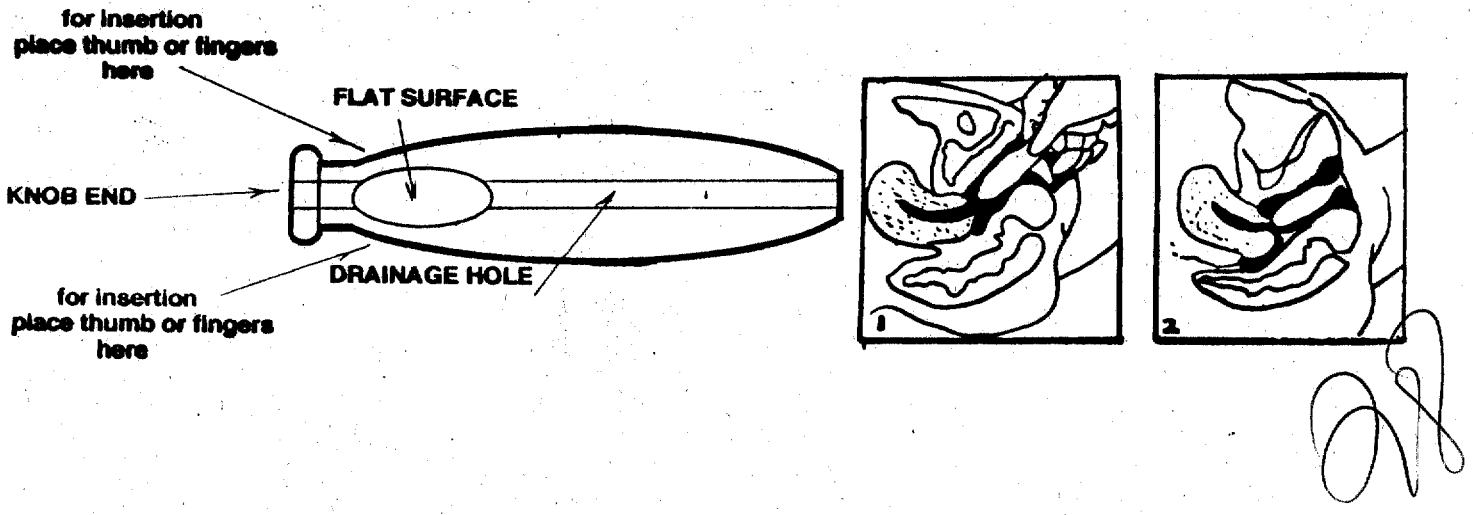
Your bowel and bladder habits should be unaffected by the Counsellor.

As a reminder, the Counsellor should be removed daily for cleaning using a mild soap and water and thoroughly rinse before reinsertion. The Counsellor is inserted and removed as diagrammed below.

1 When inserting the Counsellor, your pelvic muscles must be relaxed. With one hand spread the labia minora and with the other hand insert the blunt end of the well lubricated Counsellor into the vaginal cavity. You may use any water soluble gel to lubricate the Counsellor.

Before applying inward pressure, be sure that a flat surface of the Counsellor is clearly seen or felt and is in an upward position. You will notice that there are two flat surfaces on the Counsellor on opposite sides of the knob end. With one flat surface facing upward, grasp the Counsellor between your thumb and fingers keeping the flat surface in an upward position. Your physician should have demonstrated this maneuver to you. Now continue applying gentle inward pressure pushing the Counsellor into the vagina until it stops and the knob end is comfortably within the vagina. This will insure a flat surface will rest beneath the urethra.

2 After the Counsellor is within the vagina vault, a flattened surface (near the knob end) should be resting beneath the urethra, the external opening of the bladder. The following diagram indicates the proper insertion position. It is recommended that you wear a supportive sanitary napkin when the Counsellor is in place.



Patient Instructions - Adverse Effects

Recommended Follow-up for Nichols Counsellor Wearers

A. Immediately report any discomfort to your physician.

B. Call your physician if the Counsellor should fall out.

C. Return for a follow-up examination within 24 hours.

D. Return for a second examination within three days.

E. Schedule follow-up examinations from one to two month intervals depending on your needs.

Adverse Effects

Report any of the following symptoms to your physician immediately.

- Any change in the color or consistency in your vaginal discharge.
- Any increase in the amount of vaginal discharge
- Any foul odor associated with your vaginal discharge.
- Any vaginal itching.

K920633/E

Bioteque America Inc.

Medical Products
Design & Development
Prototypes to Production

8/29/95

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HZF-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Attention: Document Mail Clerk

RE: K920633/E

NOTE: This submission is on "telephone" hold with Mridulika Virmani, Ph. D.

Dear Dr. Virmani,

This is to inform you that I have been told by (b) (4) that they have mailed their compendium for their resin (b) (4) to the FDA and it will arrive by 8/30/95. It is anticipated that (b) (4) will supply all of the necessary information you have required for the completion of our 510K 920633/E. Their Master File for (b) (4) is #682 and the compendium will supplement their Master File. I have, once again, included a copy of their letter dated 6/7/95 permitting the FDA access to their Master File and a copy of a letter dated 6/19/95 referencing the compendium.

As you are already aware, Bioteque is very anxious to conclude this 510K application and begin the marketing of this product.

Please call for any additional information.

Sincerely,

Denis Dorsey
Bioteque America, Inc.

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

(b) (4)

ISO 9001
CERTIFIED

June 19, 1995

Denis Dorsey
BIOTEQUE AMERICA INC.
340 East Maple Avenue
Suite 120
Langhorne, PA 19047

Dear Mr. Dorsey,

(b) (4) direct replacement for Dow Corning's Q7-4840. (b) (4) developed to be, in the words of the FDA, "not substantially different" than Q7-4840. In terms of appearance, processability, and performance we believe you will find (b) (4) indistinguishable from Q7-4840. Like Q7-4840, (b) (4) is a two part product where Parts A and B are combined in a 1:1 ratio.

(b) (4) testing compendium on (b) (4) is scheduled to be submitted to the FDA by August 28, 1995. This compendium will contain the results of chemical and mechanical equivalency testing as well as biological confirmatory testing as found in the FDA's *Guidance for Medical Device Manufacturers Affected by the Withdrawal of Dow Corning Silastic Materials.*

I hope you find this information helpful and complete. Please let me know if I can be of further assistance.

Sincerely

(b) (4)

21

(b) (4) [redacted]

June 7, 1995

ISO 9001
CERTIFIED

Mr. Denis Dorsey
CEO
Bioteque America, Inc.
Suite 102
340 East Maple Ave.
Langhorne, PA 19047

Dear Mr. Dorsey:

This letter authorizes the Food and Drug Administration to include by reference information in our device master file, (b) (4) [redacted] silicone elastomer, in your device submissions.

The FDA has requested that you provide this letter with your submission and include a copy of this letter in any additional copies of your submission.

Sincerely yours,

(b) (4) [redacted]

cc: Del Petraitis
File

K920633/A3

Bioteque America Inc.

Medical Products
Design & Development
Prototypes to Production

7/27/95

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HZF-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Attention: Document Mail Clerk

RE: K920633/E

NOTE: This submission is on "telephone" hold with Mridulika Virmani, Ph. D.

Dear Dr. Virmani,

This is to inform you that I have contacted (b) (4) and they have assured me that their compendium for their (b) (4) (b) (4) will be completed on or before August 28, 1995. It is expected that (b) (4) will supply all of the necessary information you have required. As you already know, Bioteque is very anxious to conclude this 510K application.

Sincerely,

Denis Dorsey
Bioteque America, Inc.

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 11, 1995

BIOTEQUE AMERICA, INC.
340 E. MAPLE AVENUE
SUITE 102
LANGHORNE, PA 19047
ATTN: DENNIS DORSEY

510(k) Number: K920633
Product: PESSARY FLEXIBLE SILICONE NICHOLS

Extended Until: 30-SEP-95

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at 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

Bioteque America Inc.

Medical Products
Design & Development
Prototypes to Production

7/7/95

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HZF-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Attention: Document Mail Clerk

RE: K920633/E NICHOLS COUNSELLOR formerly PESSARY FLEXIBLE SILICONE NICHOLS

I have received a recent enclosed letter from the FDA referencing this submission (K9200633/E) and notifying Bioteque America Inc. that this submission by Bioteque America will be held for just 30 days.

Please note that K920633 is on "telephone" hold with Mridulika Virmani, Ph. D. pending receipt of additional data from our resin (b) (4) (b) (4) s. I have been assured by Dr. Virmani that our submission is in order and we only need to wait for the (b) (4) information. I also included a letter from (b) (4) L that indicates (b) (4) testing compendium, on our selected resin, is scheduled to be submitted to the FDA by August 28, 1995.

This period exceeds our 30 day extension which, according to your letter expires on July 30, 1995. Therefore, I'm asking for a reasonable extension of time so that the (b) (4) compendium can be evaluated by Dr. Virmani. Therefore, please allow Bioteque an extension until September 15, 1995. This additional time frame should be adequate.

Thank you for your considerations.

Sincerely,

Denis Dorsey, President
Bioteque America, Inc.

FDA/CDRH/ODE/DMC

11 JUL 95 13 24

RECEIVED

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 30, 1995

BIOTEQUE AMERICA, INC.
340 E. MAPLE AVENUE
SUITE 102
LANGHORNE, PA 19047
ATTN: DENNIS DORSEY

510(k) Number: K920633
Product: PESSARY FLEXIBLE SILICONE NICHOLS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

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

Sincerely yours,

Marjorie Shulman

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

(b) (4)

[redacted]

ISO 9001
CERTIFIED

June 19, 1995

Denis Dorsey
BIOTEQUE AMERICA INC.
340 East Maple Avenue
Suite 120
Langhorne, PA 19047

Dear Mr. Dorsey,

(b) (4)

[redacted]

I hope you find this information helpful and complete. Please let me know if I can be of further assistance.

Sincerely

(b) (4)

[redacted]

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 30, 1995

BIOTEQUE AMERICA, INC.
340 E. MAPLE AVENUE
SUITE 102
LANGHORNE, PA 19047
ATTN: DENNIS DORSEY

510(k) Number: K920633
Product: PESSARY FLEXIBLE SILICONE NICHOLS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

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Sincerely yours,

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

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

From REVIEWER(S) - NAME(S) Mridulika Virmani

Subject 510(k) NUMBER K920633/S7

To THE RECORD -- It is my recommendation that the subject 510(k) Notification:

☐ Is substantially equivalent to marketed devices.

☐ Requires premarket approval. NOT substantially equivalent to marketed devices.

☒ Requires more data. Telephone Hold.

☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance? ☐ YES ☐ NO

Is this device subject to the Tracking Regulation? ☐ YES ☐ NO

Was clinical data necessary to support the review of this 510(k)? ☐ YES ☐ NO

This 510(k) contains: Truthful and Accurate Statement ☐ Requested ☐ Enclosed
(required for originals received 3-14-95 and after)

☐ A 510(k) summary OR ☐ A 510(k) statement

☐ 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 with panel and class:

Additional Product Code(s) with panel (optional):

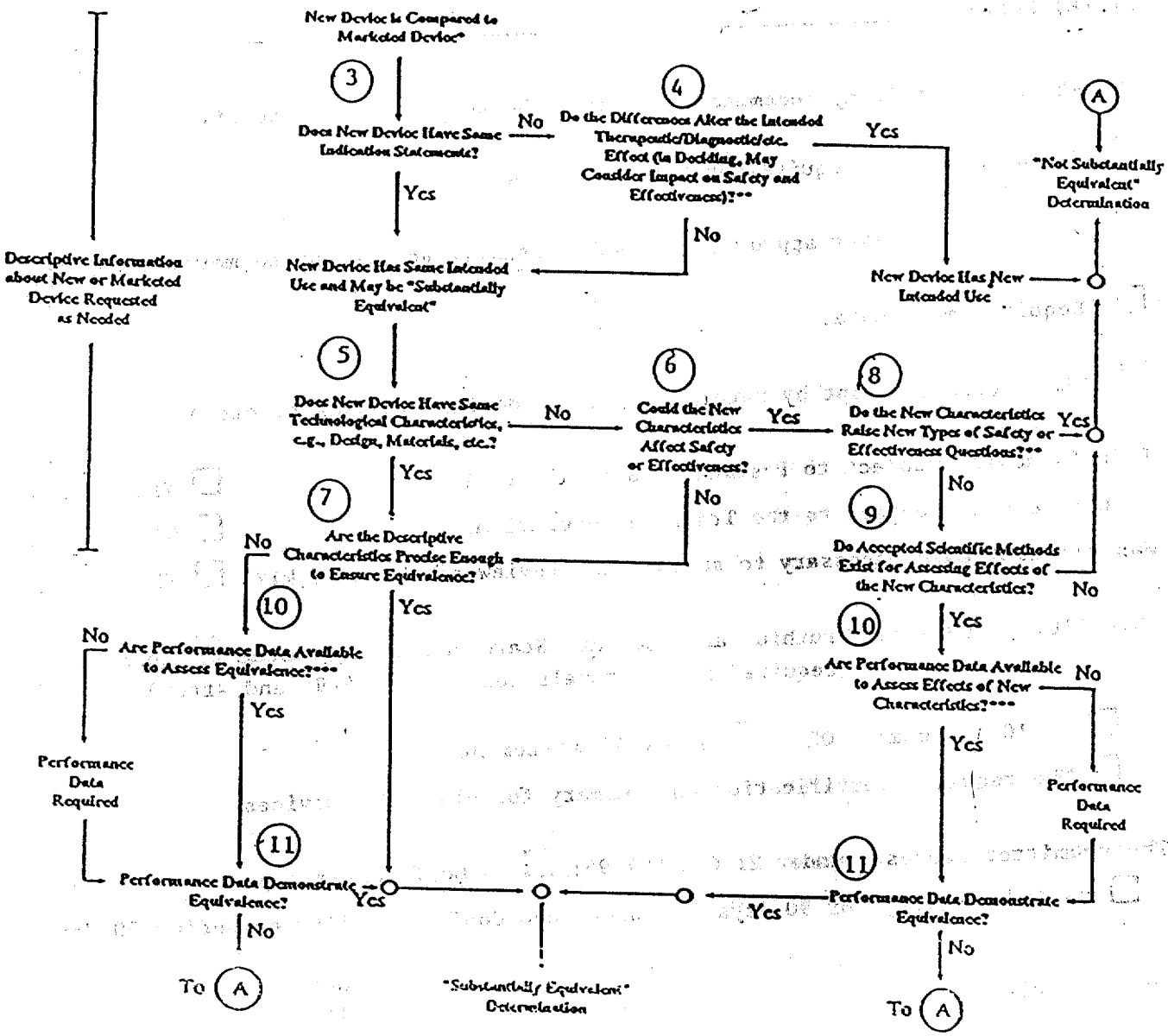
REVIEW: Colin M. Pollard (BRANCH CHIEF) OGDB (BRANCH CODE) 6/28/95 (DATE) FMF

FINAL REVIEW: (DIVISION DIRECTOR) (DATE)

Revised 3/8/95

29

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.

DIVISION OF REPRODUCTIVE, ABDOMINAL, EAR, NOSE AND THROAT AND RADIOLOGICAL DEVICES

MEMORANDUM OF TELEPHONE CONVERSATION

BETWEEN: Dennis Dorsey Date: June 28, 1995

AND: Mridulika Virmani

COMPANY: Bioteque America, Inc.

PHONE NUMBER: 215-750-8017

DOCUMENT NUMBER: K920633 /S6
(if applicable)

SUMMARY:

I called Mr. Dorsey, to convey that Bioteque American Inc. document K920633 will be on telephone hold, until we get all the information for device materials and biocompatibility. He has submitted a letter to access the (b) (4) (b) (4). This file is not complete. Company indicates that additional information on material specifications and biocompatibility will be provided by end of August, 1995. I have told Mr. Dorsey to inform FDA, when this information included in the (b) (4) until than this document will be on telephone hold.

Signed: Mridulika Virmani 6/28/95

Original to: File
Copy to: _____
_____

Bioteque America Inc.

Medical Products
Design & Development
Prototypes to Production

FAX MESSAGE

TO: Mridulika Virmani, Ph.D. — FDA
FROM: Denis Dorsey — Bioteque America, Inc.
DATE: 6/20/95

RE: K920633/E

As per our telephone conversation of 6/15/95, I am submitting the following additional information concerning K920633/E.

Page #2 of this fax message is a letter from (b) (4) indicating that their silicone material (b) (4) is a direct replacement for the Dow silicone material Q7-4840. This is at your request. Also, please note that the (b) (4) silicone is a two part product exactly like Dow's Q7-4840. Finally, paragraph 2 of the (b) (4) fax to Bioteque indicates that (b) (4) will submit a compendium of chemical and mechanical equivalency testing as well as biological comfirmatory testing on or before August 28, 1995. I sincerely hope this answers the material questions regarding this product.

Page #3 of this fax message is a corrected "Manufacturing Flow Chart". Please note that the silicone material is the (b) (4) Parts A & B.

Sincerely,

Denis Dorsey, President
Bioteque America, Inc.

called Mr. Dorsey 6/20/95 at 3:50 PM and told him that I set master file, "on hold". Until then I will keep it on hold.
MV.

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

(b) (4)

[redacted]

ISO 9001
CERTIFIED

June 19, 1995

Denis Dorsey
BIOTEQUE AMERICA INC.
340 East Maple Avenue
Suite 120
Langhorne, PA 19047

Dear Mr. Dorsey,

(b) (4)

[redacted]

I hope you find this information helpful and complete. Please let me know if I can be of further assistance.

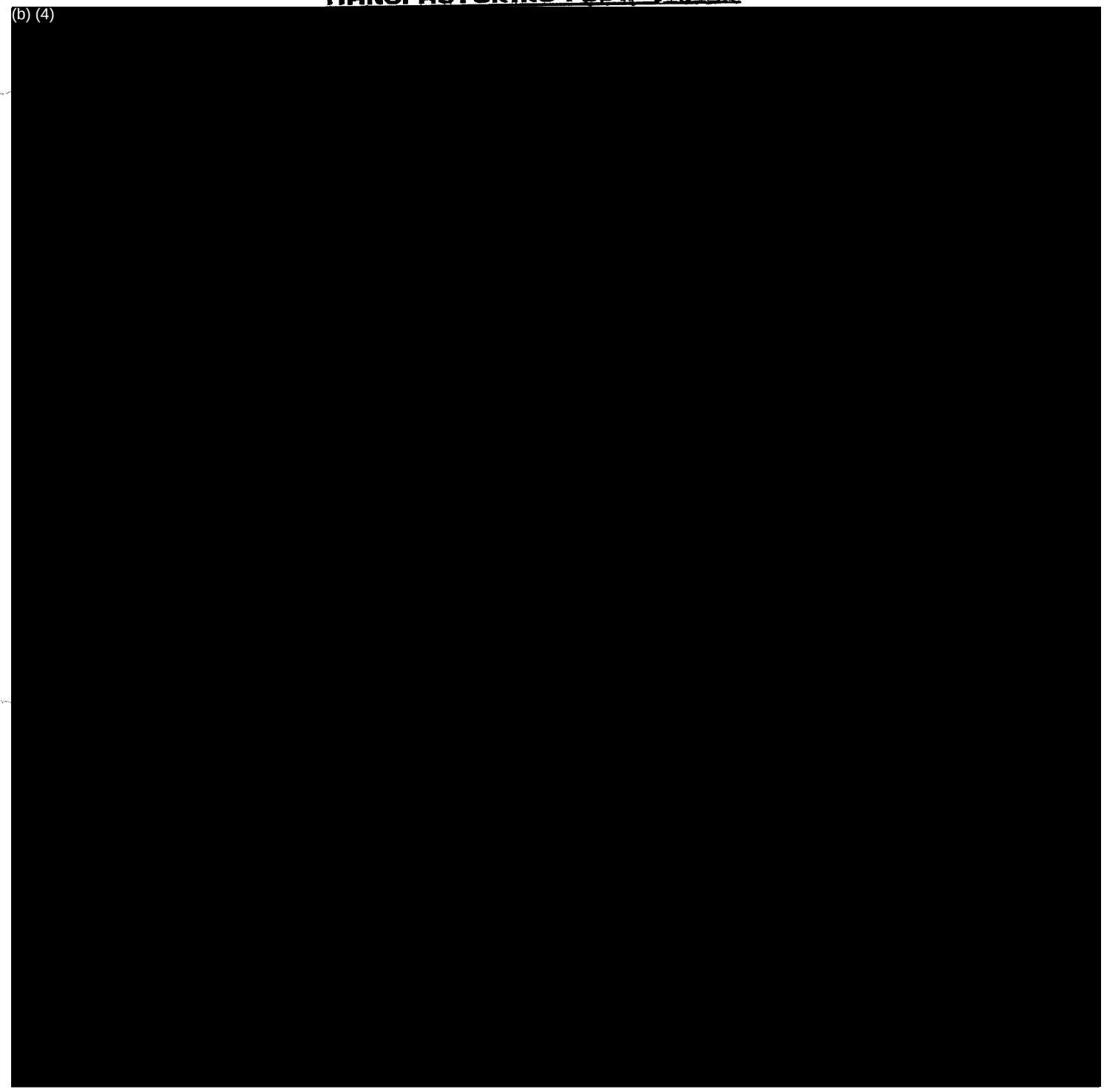
Sincerely

(b) (4)

[redacted]

MANUFACTURING FLOW CHART

(b) (4)



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)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 12, 1995

BIOTEQUE AMERICA, INC.
340 E. MAPLE AVENUE
SUITE 102
LANGHORNE, PA 19047
ATTN: DENNIS DORSEY

510(k) Number: K920633
Product: ~~PESSARY~~ FLEXIBLE ~~SILICONE~~ NICHOLS Consultor

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above 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.

The Safe Medical Devices Act of 1990, 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. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at 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

K920633/S7

Bioteque America Inc.

Medical Products
Design & Development
Prototypes to Production

6/8/95

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HZF-401)
1390 Piccard Drive
Rockville, Maryland 20850

Attention: Document Mail Clerk

RE: K920633/E

NOTE: This submission is on "telephone" hold with Mridulika Virmani, Ph. D.

This is a re-submission is due to a change of material from Applied Silicone Corporation's 40026 applied liquid silicone rubber 40 (LSR-40) material to (b) (4) (b) (4) material (b) (4) This material, the (b) (4) (b) (4) is an exact replacement material for Dow Corning's silastic™ silicone Q7-4840. Since we have made several prototypes using the Dow silastic, our manufacturing process using compression-type molding, our toolings, and production methodology will remain the same.

Also, Applied Silicone Corporation's policy is to charge $5,000.00 for the authorization letter permitting the Food and Drug Administration access to their master file. Bioteque America found this charge to be prohibitive.

Proprietary Name:

Note: Formally the PESSARY FLEXIBLE SILICONE NICHOLS

This proposed product name will be changed to the NICHOLS COUNSELLOR as per advisement of Department of Health & Human Services in letter dated May 4, 1995, Device Description & Equivalence Comparison 1. a. We would prefer not to use the name Counsellor Vaginal Mould.

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

Device Description & Equivalence Comparison

1. a. Have submitted labeling changes to our proposed literature and hence forth this device will no longer be referred to as the NICHOLS SILICONE PESSARY but rather the NICHOLS COUNSELLOR.

Materials

2. I have review our intended use of DOW silastic™ silicone with Mr. Stephen Smith of DOW CORNING, Midland, MI 48640, by phone on 5/11/95 and as the result of this conversation, the material will be changed from Dow Corning's silastic™ silicone Q7-4840 to (b) (4) which is an exact equivalent of Dow's Q7-4840.

Please see NuSil Silicone Technology's data submitted to Bioteque America concerning material specifications and a letter permitting the Food and Drug Administration access to their (b) (4)

Manufacturing Process (no changes):

(b) (4)

1.0 SCOPE

These specifications and procedures pertain to the following product:
Nichols Counsellor (Vaginal Mould)
P/N: C116S (small), C124M (medium), C133L (large)

2.0 DESCRIPTION

2.1 See product descriptions in attachments for the design mechanical drawing and dimensional specifications.

2.2 The Nichols Counsellor shall be manufactured from a stable medical grade silicone supplied by NuSil Technology Corporation.

2.3 The Nichols Counsellors will have a smooth surface finish, blemish free and within specified tolerances.

3.0 FORMULATION

3.1 The silicone compound shall be maintained on file by the manufacturer and shall be referenced and recorded by the Nichols Counsellor lot control code. NuSil material designated as NuSil MED-4840 is to be used to produce the part.

4.0 GENERAL REQUIREMENTS

4.1 WORKMANSHIP - The Counsellors shall be clean and free from physical damage.

4.2 CODING - Each lot shall be coded with a control number and this code number with size and these numbers must be imprinted on the instructional sheet that accompanies the part. All records pertaining to the control number will be kept on file at the manufacturing site.

5.0 SPECIAL REQUIREMENTS

5.1 PHYSICAL PROPERTIES - The silicone used for the Nichols Counsellor shall have the properties of MED-4840 as per NuSil's product information sheets and specifications.

5.2 AGED PROPERTIES - The silicone used for the Nichols Counsellor shall not, after aging, vary from the original properties by more than 20%.

6.0 GENERAL QA REQUIREMENTS

6.1 SYMMETRY - Satisfactory if all dimensions of Counsellor are within +/- 1mm of design standard nominal values as per drawing. Measurements to be made with digital read-out micrometer and recorded. (see 6.3.1).

6.2 LOT CODE IDENTIFICATION - Denotes month and year of manufacture.

6.3 PHYSICAL DIMENSIONS - see drawing

6.3.1 Using digital read-out micrometer measure dimensions designated as A the overall length of the product, B the maximum diameter, and C the distal end of the product. All dimensions should be within +/- 1mm, well within manufacturing standard deviations as per STANDARD DEVIATION chart. Standard deviations were calculated based on minimum production run of product using equivalent material.

6.4 COSMETIC BLEMISHES - refers to dirt, foreign material, and mold parting lines (if any).

6.5 INTEGRITY - Be sure knob is as per engineering drawing. Check that part has flat surfaces near knob on opposite sides of part as per engineering drawing. Be sure distal end C is blunt and free of burrs and/or sprues. Part should be smooth and without cosmetic blemishes.

7.0 PACKAGING AND LABELING REQUIREMENTS

7.1 The Nichols Counsellor shall be packaged in medically clean poly bags with physician/patient instructions included. Instructions labeled as per 4.2.

7.2 The physician/patient instructions will include the following:

Bioteque America, Inc.
340 E. Maple Avenue, Suite #102
Langhorne, PA 19047

Nichols Counsellor
C116S or C125M or C133L (just a single size)
LOT CODE: _____ (see section 6.2)

8.0 CERTIFICATE OF COMPLIANCE

8.1 Each shipment shall contain a certificate of compliance which is to include:

a. A statement that the product has been manufactured in compliance with this specification.

b. Complete list of the number of units manufactured, specific sizes, and lot number identification.

See Exhibit A

9.0 OTHER REQUIREMENTS

9.1 Provide Bioteque America, Inc. with the following additional information:

a. All part numbers and quantities

b. Confirmation of Purchase Order Number

9.2 All parts not meeting this specification may be returned for replacement.

9.3 Manufacturing records shall be retained for a minimum of 3 years and be made available upon request.

9.4 Any changes or amendments to this specification shall be written and approved using only the following procedure:

a. The proposed change will be in writing by the appropriate party and will include those pages and sections affected. Includes engineering design drawings.

b. The draft of changes must be circulated for review and comment by Bioteque America, Inc. located at 340 E. Maple Avenue, Suite #102, Langhorne, PA 19047.

c. After informal approval of the draft, the change will be written into the specification and the old material deleted.

d. Enter the effective date of change and initial. Sign and date the approval/revision sheet.

10. ACCEPTABLE QUALITY LEVEL (AQL)

10.1 Part must meet the quality assurance testing procedures.

10.2 At quality control (before shipment) at least 5% of the product should be re-measured for sizing and cosmetically rechecked (including packaging).

Material Toxicity

5. Additional chemicals are not used in the manufacturing process.

Labeling

6. A copy of the instructions is included in this re-submission.
7. The word "marked" does not appear.

Respectfully submitted,

Denis Dorsey
Bioteque America, Inc.

CERTIFICATE OF COMPLIANCE

WE CERTIFY THAT THE MATERIAL USED IN THE MANUFACTURE OF THE FOLLOWING COMPONENT IS A MEDICAL GRADE SILICONE PRODUCT PRODUCED BY THE APPLIED SILICONE CORPORATION AND THAT THEY COMPLY WITH OUR SPECIFICATIONS, STANDARDS, AND QUALITY ASSURANCE PRACTICES.

PART NO.	P.O. NO.	LOT NO.	QUANTITY	SHIP DATE

Quality Assurance Manager

date

Exhibit A

(b) (4) [redacted]

June 7, 1995

ISO 9001
CERTIFIED

Mr. Denis Dorsey
CEO
Bioteque America, Inc.
Suite 102
340 East Maple Ave.
Langhorne, PA 19047

Dear Mr. Dorsey:

This letter authorizes the Food and Drug Administration to include by reference information in our device (b) (4) [redacted] silicone elastomer, in your device submissions.

The FDA has requested that you provide this letter with your submission and include a copy of this letter in any additional copies of your submission.

Sincerely yours,

(b) (4) [redacted]

(b) (4)

[redacted]

FAX TO THE FOLLOWING NUMBER: 215 - 750 - 8073

THE FOLLOWING PAGE(S) ARE FOR: Denis Dorsey

FIRM/COMPANY NAME: BIOTEQUE AMERICA, INC.

FROM: Del Petratis

SUBJECT: MAF Release & MSDS for MED-4890

FAX OPERATOR

DATE: 6-7-95 TIME: A.M. P.M. 2:30

TOTAL NUMBER OF PAGES: (THIS INFORMATION SHEET PLUS 13 PAGE(S)

REPLY NEEDED: ____ YES ____ NO

IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL BACK IMMEDIATELY.

OUR TELEPHONE NUMBER IS (805) 684-8780

OUR FACSIMILLE NUMBER IS (805) 684-2365

Denis Dorsey:

The originals will be mailed.

Del Petratis

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Standard Deviation

MANUFACTURING FLOW CHART

(b) (4)

DISTRIBUTED BY:
BIO•AM™
Bioteque America, Inc.
340 East Maple Avenue
Langhorne, PA 19047
Tel. (215) 750-8071
Fax (215) 750-8073

Bioteque America, Inc.

The NICHOLS COUNSELLOR

(OBTURATOR-TYPE)

The Nichols Counsellor (Obturator-Type) is available in three sizes.

Product #: C116S (small) C125M (medium) C133L (large)

Caution: Federal law restricts this device to or on the order of a physician.

Indications: To support or distend the vaginal canal.

Contraindications: Vaginal counsellors are contraindicated in acute genital tract infections or in the presence of pelvic infections or lacerations.

Instructions for the Physician: Following the construction of a neovagina or any portion thereof, or following a vaginalplasty operations performed to enlarge a small vagina, or for the relief of viginismus, it is usually desired to support or distend the vaginal canal with a device to prevent unwanted contraction of the scar or to relax the muscles that surround the vagina. Such a counsellor or obturator should be simple, smooth surfaced, light in weight, capable of removal and insertion by the patient and affordable. It should be available in various sizes. Since even a silicone obturator is a foreign body in the vagina, any vaginal secretions must route through the obturator for drainage from the vault of the vagina. This silicone vaginal counsellor designed and produced in various sizes, meets the above criteria.

Instruct the patient to report any discomfort. The patient should return in twenty-four hours for the first examination. The vaginal obturator should be removed every day or two for cleaning and can be washed with a mild soap and water and then rinsed before reinsertion. Have the patient return in about three days for the second examination and then schedule monthly return visits.

Adverse Reactions: During each visit, the vagina should be checked for evidence of unnecessary pressure or allergic reactions.

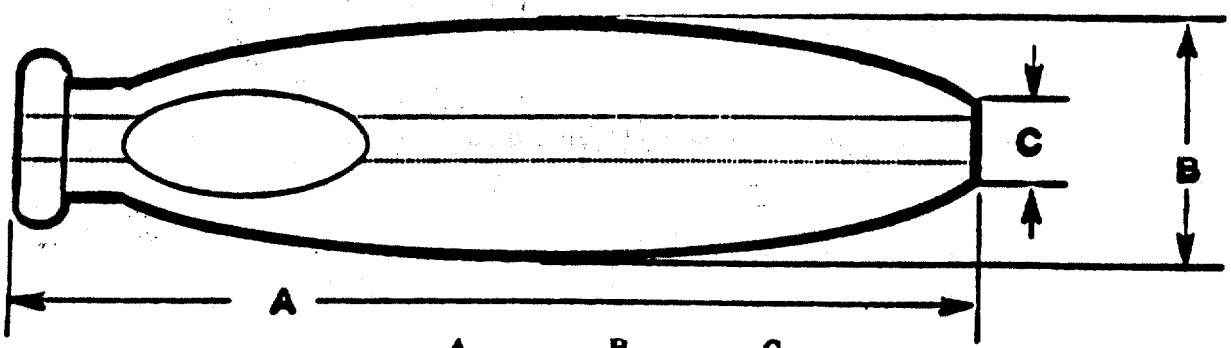
Precautions: The patient should be questioned concerning douching, discharge, disturbance of bowel function and urination.

Instructions for the Patient: Your doctor has recognized the need for wearing a device or obturator within the vagina that will keep the vaginal cavity from contracting during its healing phase or to relax the spasms of the muscles around the vaginal entrance. When the obturator is in its place you may be conscious of a mild feeling of pressure, but there should be no pain. Should the device become painful, bring the matter promptly to your physician's attention. There is a small knob at the outside end of the obturator that can be grasped to facilitate its insertion and removal.

When inserting the obturator, your pelvic muscles must be relaxed. With one hand separate the labia minora and with the other insert the blunt end of the well lubricated (use any water soluble gel) obturator into the vaginal cavity and gently make pressure, pushing the obturator into the vagina until it stops and the knob end is comfortably within the vagina. The obturator should be turned so that one flattened surface near the tip (knob) will come to rest beneath the urethra (the external opening into the bladder). It is recommended that you wear a supportive sanitary napkin when the obturator is in place.

The obturator should be removed from time to time, as your physician will instruct, washed with soap and water and replaced.

These instruction are courtesy of David H. Nichols, MD
Sizes available are small, medium, and large



	A	B	C
SMALL	116.75 mm	30.75 mm	13.75 mm
MEDIUM	125.50 mm	33.50 mm	14.75 mm
LARGE	133.75 mm	41.70 mm	15.75 mm

PATENT PENDING

NO

DISTRIBUTED BY:
BIO•AM™
Bioteque America, Inc.
340 East Maple Avenue
Langhorne, PA 19047
Tel. (215) 750-8071
Fax (215) 750-8073

Bioteque America, Inc.

The NICHOLS COUNSELLOR

(OBTURATOR-TYPE)

LOT 831485
C125M
SAMPLE

The Nichols Counsellor (Obturator-Type) is available in three sizes.

Product #: C116S (small) C125M (medium) C133L (large)

Caution: Federal law restricts this device to or on the order of a physician.

Indications: To support or distend the vaginal canal.

Contraindications: Vaginal counsellors are contraindicated in acute genital tract infections or in the presence of pelvic infections or lacerations.

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THESE INSTRUCTIONS INCLUDED WITH PART

DISTRIBUTED BY:
BIO•AM™
Bioteque America, Inc.
340 East Maple Avenue
Langhorne, PA 19047
Tel. (215) 750-8071
Fax (215) 750-8073

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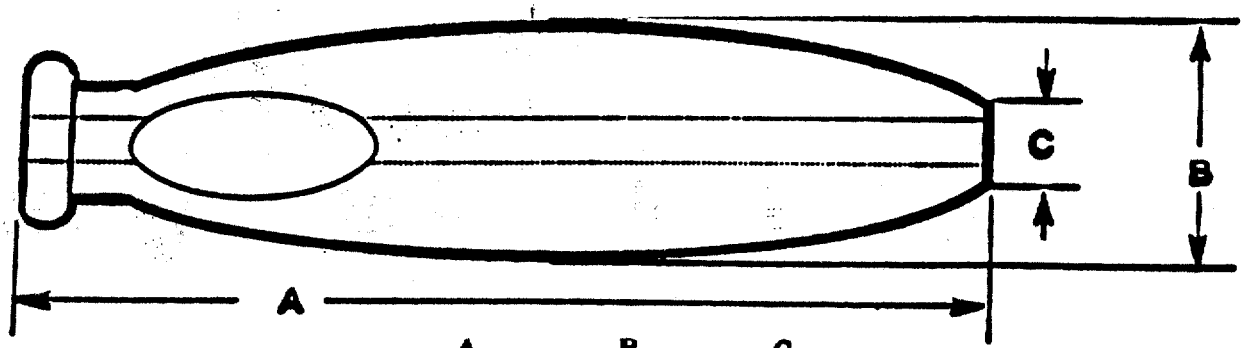
The obturator should be removed from time to time, as your physician will instruct, washed with soap and water and replaced.

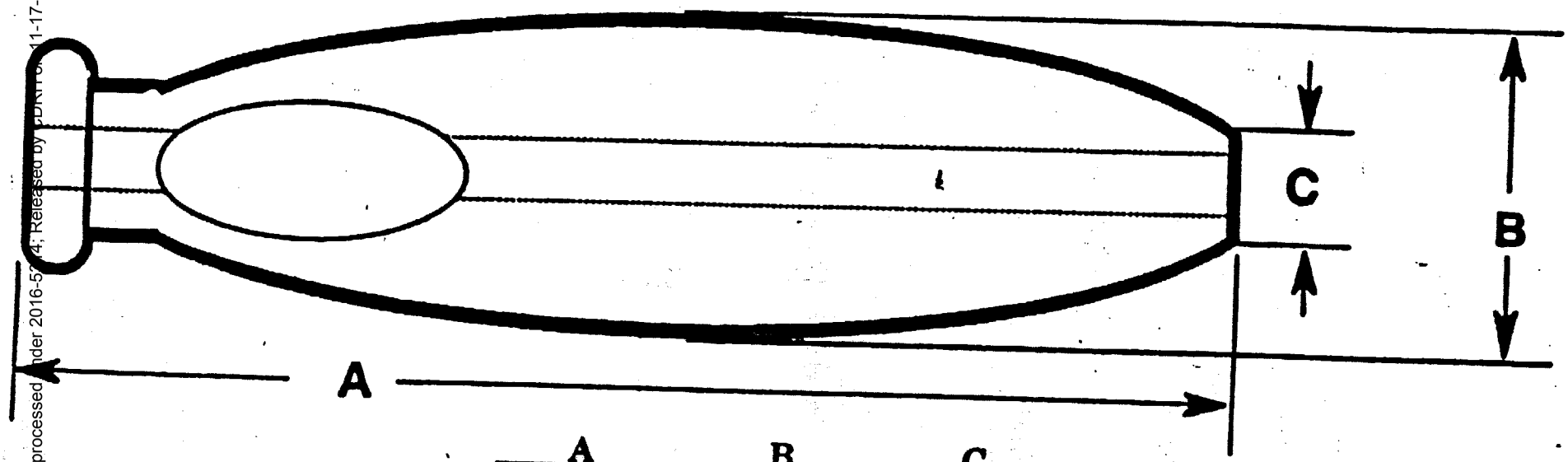
These instruction are courtesy of David H. Nichols, MD
Sizes available are small, medium, and large



	A	B	C
SMALL	116.75 mm	30.75 mm	13.75 mm
MEDIUM	125.50 mm	33.50 mm	14.75 mm
LARGE	133.75 mm	41.70 mm	16.76 mm

PATENT PENDING

MEDIUM



	A	B	C
SMALL	116.75 mm	30.75 mm	13.75 mm
MEDIUM	125.50 mm	33.50 mm	14.75 mm
LARGE	133.75 mm	41.70 mm	15.75 mm

PATENT PENDING

NOMINAL VALUES

Bioteque America Inc.

Medical Products
Design & Development
Prototypes to Production

PREMARKET NOTIFICATION
510(k) STATEMENT
(AS REQUIRED BY 21 CFR 807.93)

I certify that, in my capacity as President of Bioteque America, Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including and adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information as defined in 21 CFR 20.61.

Denis P. Dorsey

5/25/95

K920633/E

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

Bioteque America Inc.

Medical Products
Design & Development
Prototypes to Production

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(AS REQUIRED BY 21 CFR 807.87(j))

I certify that, in my capacity as President of Bioteque America, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that not material fact has been omitted.

Denis P. Dorsey

5/25/95

K920633/E

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 09, 1995

BIOTEQUE AMERICA, INC.
340 E. MAPLE AVENUE
SUITE 102
LANGHORNE, PA 19047
ATTN: DENNIS DORSEY

510(k) Number: K920633
Product: PESSARY FLEXIBLE SILICONE NICHOLS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

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

Sincerely yours,

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

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

From REVIEWER(S) - NAME(S) Mridulika Virmani

Subject 510(k) NUMBER K920633/S6

To THE RECORD -- It is my recommendation that the subject 510(k) Notification:

☐ Is substantially equivalent to marketed devices.

☐ Requires premarket approval. NOT substantially equivalent to marketed devices.

☒ Requires more data. Telephone Hold

☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance? ☐ YES ☐ NO

Is this device subject to the Tracking Regulation? ☐ YES ☐ NO

Was clinical data necessary to support the review of this 510(k)? ☐ YES ☐ NO

This 510(k) contains: Truthful and Accurate Statement ☐ Requested ☐ Enclosed
(required for originals received 3-14-95 and after)

☐ A 510(k) summary OR ☐ A 510(k) statement

☐ 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 with panel and class:

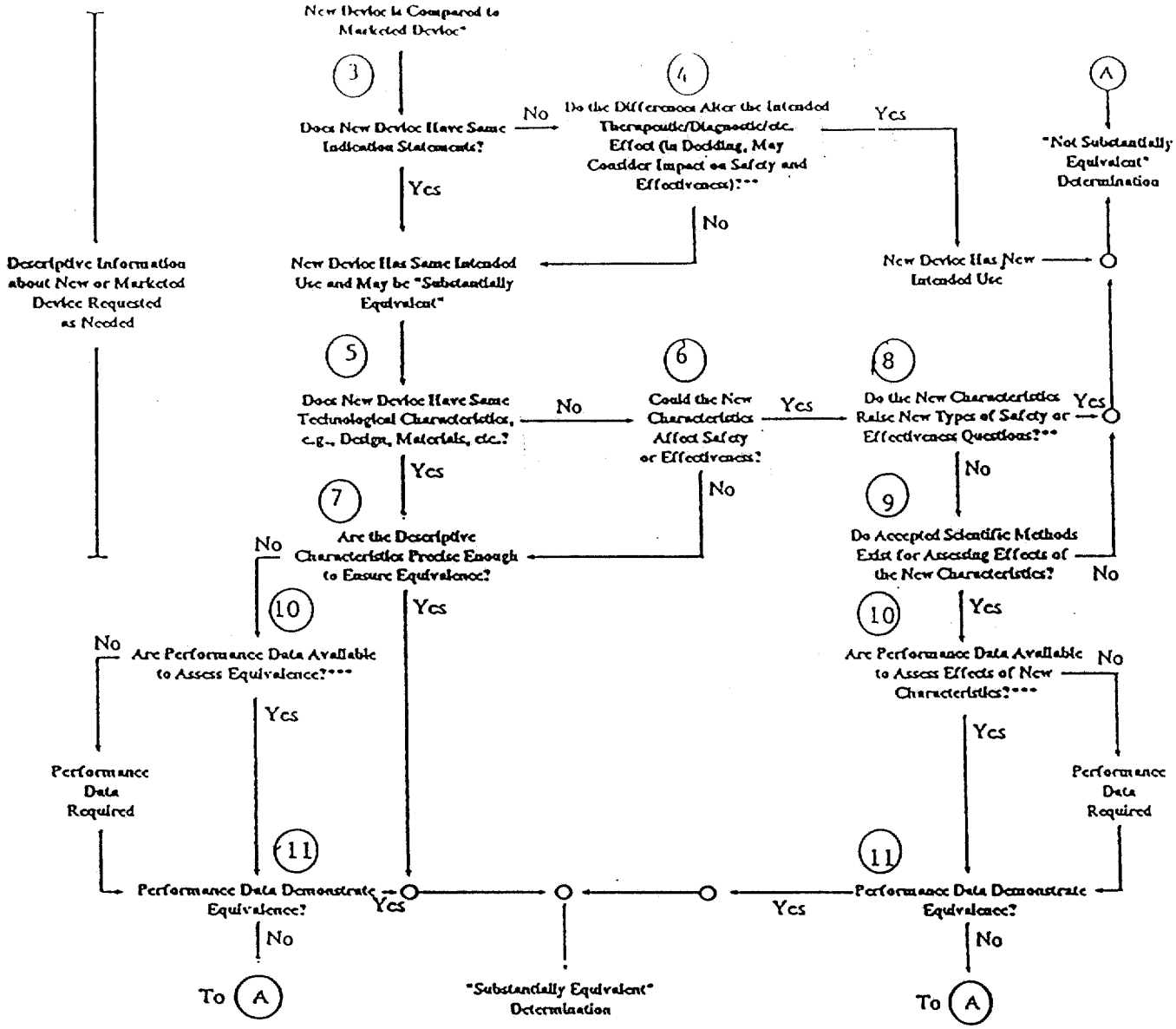
Additional Product Code(s) with panel (optional):

REVIEW: Colin M Bolland (BRANCH CHIEF) OGDB (BRANCH CODE) 6/7/95 (DATE) (FMF)

FINAL REVIEW: (DIVISION DIRECTOR) (DATE)

Revised 3/8/95

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.

DIVISION OF REPRODUCTIVE, ABDOMINAL, EAR, NOSE AND THROAT AND RADIOLOGICAL DEVICES

MEMORANDUM OF TELEPHONE CONVERSATION

BETWEEN: Dennis Dorsey Date: June 7, 1995

AND: Mridulika Virmani

COMPANY: Bioteque America, Inc.

PHONE NUMBER: 215-750-8017

DOCUMENT NUMBER: K920633 /S6
(if applicable)

SUMMARY:

(b) (4)

[redacted]

Signed: Mridulika Virmani 6/7/95

OK CMP 6/7/95

Original to: File
Copy to: _____
_____

DRAERD REVIEWER RECORD FOR 510(K)s, IDEs, AND PMA SUPPLEMENTS

Document Control No._____ Principal Reviewer_____

Date Assigned_____

Consulting reviews designated, as appropriate, by Branch Chief and lead reviewer, at the beginning of the review

Specialty	Review Needed?		Reviewer	Dates	
	Yes	No		Sent	Returned
Clinical	____	____	_____	_____	_____
Engineering/ Physics	____	____	_____	_____	_____
Chemistry/ Biomaterials	____	____	_____	_____	_____
Biological/ Sterility	____	____	_____	_____	_____
Toxicology/ Biocompatibility	____	____	_____	_____	_____
Statistics	____	____	_____	_____	_____
Other_____	____	____	_____	_____	_____

3/93

90

. DRAERD Quality Control -- to be completed by the Associate Director and, as appropriate, by the designated Medical Officer.

A. Associate Director QC Overview -- medical QC overview of this submission is believed necessary.

YES NO

___ ___

Initials/Date

B. If YES is noted above, Medical Officer QC Overview --

(1) Examination of the specialty reviews indicate there are remaining clinical issues that should be addressed -- see attached sheet for summary.

Initials/Date

(2) In my opinion, all pertinent clinical issues have been adequately addressed.

Medical Officer/Date
Final Signoff

Assoc. Director/Date
Final Signoff

4/93

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 02, 1995

BIOTEQUE AMERICA, INC.
340 E. MAPLE AVENUE
SUITE 102
LANGHORNE, PA 19047
ATTN: DENNIS DORSEY

510(k) Number: K920633
Product: PESSARY FLEXIBLE SILICONE NICHOLS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above 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.

The Safe Medical Devices Act of 1990, 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. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at 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

K920633/S6

Biotegue America Inc.

Medical Products
Design & Development
Prototypes to Production

31 Mar 95 14 52

FDA/CDRH/CDE/DMC

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HZF-401)
1390 Piccard Drive
Rockville, Maryland 20850

Attention: Document Mail Clerk

RE: K920633/E

Proprietary Name:

Note: Formally the PESSARY FLEXIBLE SILICONE NICHOLS

This proposed product name will be changed to the NICHOLS COUNSELLOR as per advisement of Department of Health & Human Services in letter dated May 4, 1995, Device Description & Equivalence Comparison 1. a. We would prefer not to use the name Counsellor Vaginal Mould.

Device Description & Equivalence Comparison

1. a. Have submitted labeling changes to our proposed literature and hence forth this device will no longer be referred to as the NICHOLS SILICONE PESSARY but rather the NICHOLS COUNSELLOR.

Materials

2. I have review our intended use of DOW silastic™ silicone with Mr. Stephen Smith of DOW CORNING, Midland, MI 48640, by phone on 5/11/95 and as the result of this conversation, the material will be changed from Dow Corning's silastic™ silicone Q7-4840 to the Applied Silicone Corporation's 40026 applied liquid silicone rubber 40 (LSR-40) material.

Please see Applied Silicone Corporation's attachments concerning the material specifications and the related biocompatibility information.

For details concerning Applied Silicone's Master Files, the FDA can contact:

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

(b) (4) [redacted]

Manufacturing Process:

(b) (4) [redacted]

4. a Description of quality assurance testing procedures

The Nichols Counsellor is manufactured using the following component specifications and procedures:

COMPONENT PART SPECIFICATIONS

Nichols Counsellor (Vaginal Mould)
P/N: C116S (small), C124M (medium), C133L (large)
Effective: January, 1995
Silicone Manufacturer: Applied Silicone Corporation

1.0 SCOPE

These specifications and procedures pertain to the following product:
Nichols Counsellor (Vaginal Mould)
P/N: C116S (small), C124M (medium), C133L (large)

2.0 DESCRIPTION

2.1 See product descriptions on page _____ for the design mechanical drawing and dimensional specifications.

2.2 The Nichols Counsellor shall be manufactured from a stable medical grade silicone.

2.3 The Nichols Counsellors will have a smooth surface finish, blemish free and within specified tolerances.

3.0 FORMULATION

(b) (4)

[redacted]

4.0 GENERAL REQUIREMENTS

4.1 WORKMANSHIP - The Counsellors shall be clean and free from physical damage.

4.2 CODING - Each lot shall be coded with a control number and this code number with size ~~and these numbers~~ must be imprinted on the instructional sheet that accompanies the part. All records pertaining to the control number will be kept on file at the manufacturing site.

5.0 SPECIAL REQUIREMENTS

5.1 PHYSICAL PROPERTIES - The silicone used for the Nichols Counsellor shall have the properties of #40026 as per Applied Silicone Corporation's product information sheet, i.e., shore A units @ 40, tensile strength (psi) @ 980, elongation (%) 450, tear strength (ppi) @ 170, specific gravity @ 1.12, compression set 22 hours @ 177°C 55%, and linear shrinkage (%) @ 2.0%, etc.

5.2 AGED PROPERTIES - The silicone used for the Nichols Counsellor shall not, after aging, vary from the original properties by more than 20%.

6.0 GENERAL QA REQUIREMENTS

6.1 SYMMETRY - Satisfactory if all dimensions of Counsellor are within +/- 1mm of design standard nominal values as per drawing. Measurements to be made with digital read-out micrometer and recorded. (see 6.3.1).

6.2 LOT CODE IDENTIFICATION - Denotes month and year of manufacture.

6.3 PHYSICAL DIMENSIONS - see drawing

6.3.1 Using digital read-out micrometer measure dimensions designated as A the overall length of the product, B the maximum diameter, and C the distal end of the product. All dimensions should be within +/- 1mm, well within manufacturing standard deviations as per STANDARD DEVIATION chart.

6.4 COSMETIC BLEMISHES - refers to dirt, foreign material, and mold parting lines (if any).

6.5 INTEGRITY - Be sure knob is as per engineering drawing. Check that part has flat surfaces near knob on opposite sides of part as per engineering drawing. Be sure distal end C is blunt and free of burrs and/or sprues. Part should be smooth and without cosmetic blemishes.

7.0 PACKAGING AND LABELING REQUIREMENTS

7.1 The Nichols Counsellor shall be packaged in medically clean poly bags with physician/patient instructions included. Instructions labeled as per 4.2.

7.2 The physician/patient instructions will include the following:

Bioteque America, Inc.
340 E. Maple Avenue, Suite #102
Langhorne, PA 19047

Nichols Counsellor
C116S or C125M or C133L (just a single size)
LOT CODE: _____ (see section 6.2)

8.0 CERTIFICATE OF COMPLIANCE

8.1 Each shipment shall contain a certificate of compliance which is to include:

a. A statement that the product has been manufactured in compliance with this specification.

b. Complete list of the number of units manufactured, specific sizes, and lot number identification.

See Exhibit A

9.0 OTHER REQUIREMENTS

9.1 Provide Bioteque America, Inc. with the following additional information:

a. All part numbers and quantities

b. Confirmation of Purchase Order Number

9.2 All parts not meeting this specification may be returned for replacement.

9.3 Manufacturing records shall be retained for a minimum of 3 years and be made available upon request.

9.4 Any changes or amendments to this specification shall be written and approved using only the following procedure:

a. The proposed change will be in writing by the appropriate party and will include those pages and sections affected. Includes engineering design drawings.

b. The draft of changes must be circulated for review and comment by Bioteque America, Inc. located at 340 E. Maple Avenue, Suite #102, Langhorne, PA 19047.

c. After informal approval of the draft, the change will be written into the specification and the old material deleted.

d. Enter the effective date of change and initial. Sign and date the approval/revision sheet.

10. ACCEPTABLE QUALITY LEVEL (AQL)

10.1 Part must meet the quality assurance testing procedures.

10.2 At quality control (before shipment) at least 5% of the product should be re-measured for sizing and cosmetically rechecked (including packaging).

Material Toxicity

5. Additional chemicals are not used in the manufacturing process.

Labeling

6. A copy of the instructions is included in this re-submission.
7. The word "marked" does not appear.

Respectfully submitted,

Denis Dorsey
Bioteque America, Inc.

CERTIFICATE OF COMPLIANCE

WE CERTIFY THAT THE MATERIAL USED IN THE MANUFACTURE OF THE FOLLOWING COMPONENT IS A MEDICAL GRADE SILICONE PRODUCT PRODUCED BY THE APPLIED SILICONE CORPORATION AND THAT THEY COMPLY WITH OUR SPECIFICATIONS, STANDARDS, AND QUALITY ASSURANCE PRACTICES.

PART NO.	P.O. NO.	LOT NO.	QUANTITY	SHIP DATE

_____
Quality Assurance Manager

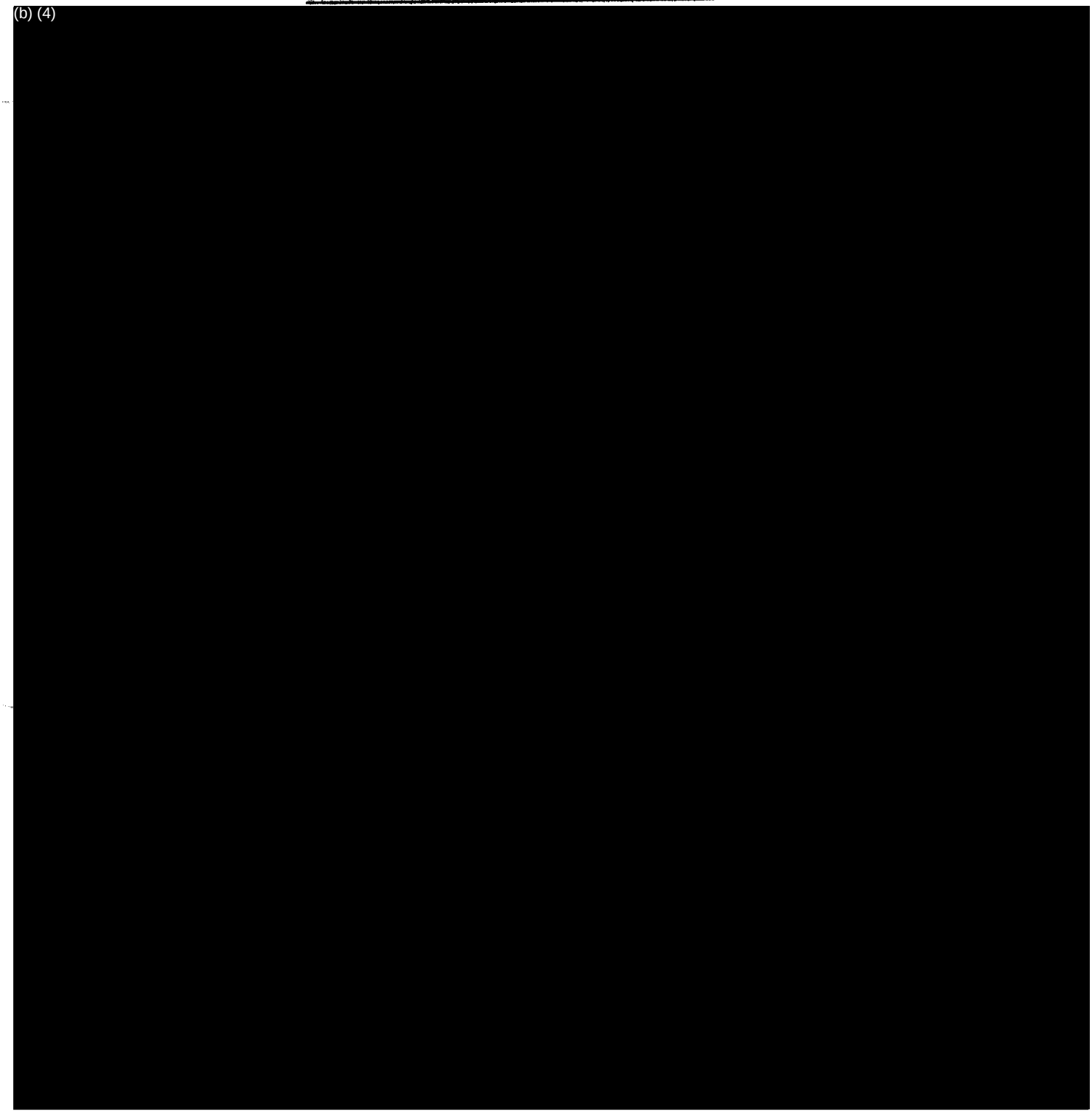
_____
date

Exhibit A

(b) (4) Standard Deviation

MANUFACTURING FLOW CHART

(b) (4)



DISTRIBUTED BY:
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Bioteque America, Inc.
340 East Maple Avenue
Langhorne, PA 19047
Tel. (215) 750-8071
Fax (215) 750-8073

Bioteque America, Inc.

The NICHOLS COUNSELLOR

(OBTURATOR-TYPE)

The Nichols Counsellor (Obturator-Type) is available in three sizes.

Product #: C116S (small) C125M (medium) C133L (large)

Caution: Federal law restricts this device to or on the order of a physician.

Indications: To support or distend the vaginal canal.

Contraindications: Vaginal counsellors are contraindicated in acute genital tract infections or in the presence of pelvic infections or lacerations.

Instructions for the Physician: Following the construction of a neovagina or any portion thereof, or following a vaginalplasty operations performed to enlarge a small vagina, or for the relief of viginismus, it is usually desired to support or distend the vaginal canal with a device to prevent unwanted contraction of the scar or to relax the muscles that surround the vagina. Such a counsellor or obturator should be simple, smooth surfaced, light in weight, capable of removal and insertion by the patient and affordable. It should be available in various sizes. Since even a silicone obturator is a foreign body in the vagina, any vaginal secretions must route through the obturator for drainage from the vault of the vagina. This silicone vaginal counsellor designed and produced in various sizes, meets the above criteria.

Instruct the patient to report any discomfort. The patient should return in twenty-four hours for the first examination. The vaginal obturator should be removed every day or two for cleaning and can be washed with a mild soap and water and then rinsed before reinsertion. Have the patient return in about three days for the second examination and then schedule monthly return visits.

91

Adverse Reactions: During each visit, the vagina should be checked for evidence of unnecessary pressure or allergic reactions.

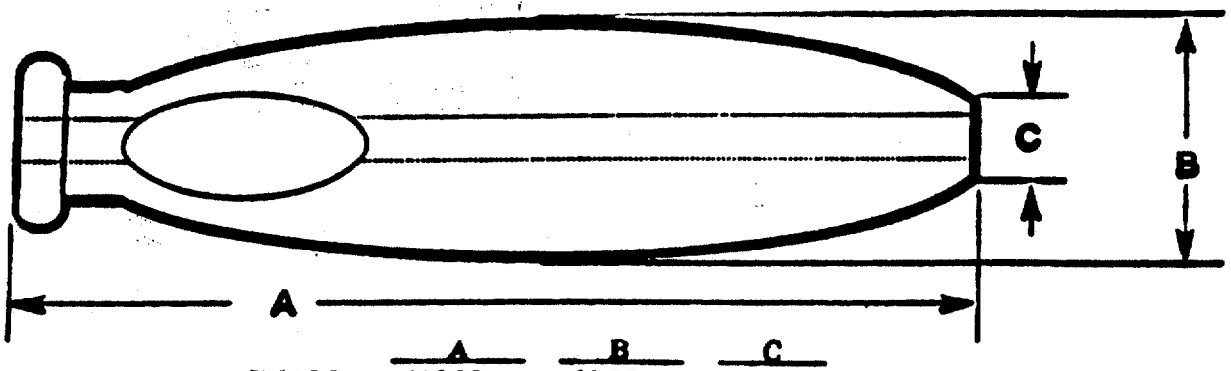
Precautions: The patient should be questioned concerning douching, discharge, disturbance of bowel function and urination.

Instructions for the Patient: Your doctor has recognized the need for wearing a device or obturator within the vagina that will keep the vaginal cavity from contracting during its healing phase or to relax the spasms of the muscles around the vaginal entrance. When the obturator is in its place you may be conscious of a mild feeling of pressure, but there should be no pain. Should the device become painful, bring the matter promptly to your physician's attention. There is a small knob at the outside end of the obturator that can be grasped to facilitate its insertion and removal.

When inserting the obturator, your pelvic muscles must be relaxed. With one hand separate the labia minora and with the other insert the blunt end of the well lubricated (use any water soluble gel) obturator into the vaginal cavity and gently make pressure, pushing the obturator into the vagina until it stops and the knob end is comfortably within the vagina. The obturator should be turned so that one flattened surface near the tip (knob) will come to rest beneath the urethra (the external opening into the bladder). It is recommended that you wear a supportive sanitary napkin when the obturator is in place.

The obturator should be removed from time to time, as your physician will instruct, washed with soap and water and replaced.

These instruction are courtesy of David H. Nichols, MD
Sizes available are small, medium, and large



	A	B	C
SMALL	116.75 mm	30.75 mm	13.75 mm
MEDIUM	125.50 mm	33.50 mm	14.75 mm
LARGE	133.75 mm	41.70 mm	15.75 mm

PATENT PENDING

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Bioteque America, Inc.
340 East Maple Avenue
Langhorne, PA 19047
Tel. (215) 750-8071
Fax (215) 750-8073

Bioteque America, Inc.

The NICHOLS COUNSELLOR

(OBTURATOR-TYPE)

LOT 831485
C125M
SAMPLE

The Nichols Counsellor (Obturator-Type) is available in three sizes.

Product #: C116S (small) C125M (medium) C133L (large)

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Indications: To support or distend the vaginal canal.

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THESE INSTRUCTIONS INCLUDED WITH PART 93

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Langhorne, PA 19047
Tel. (215) 750-8071
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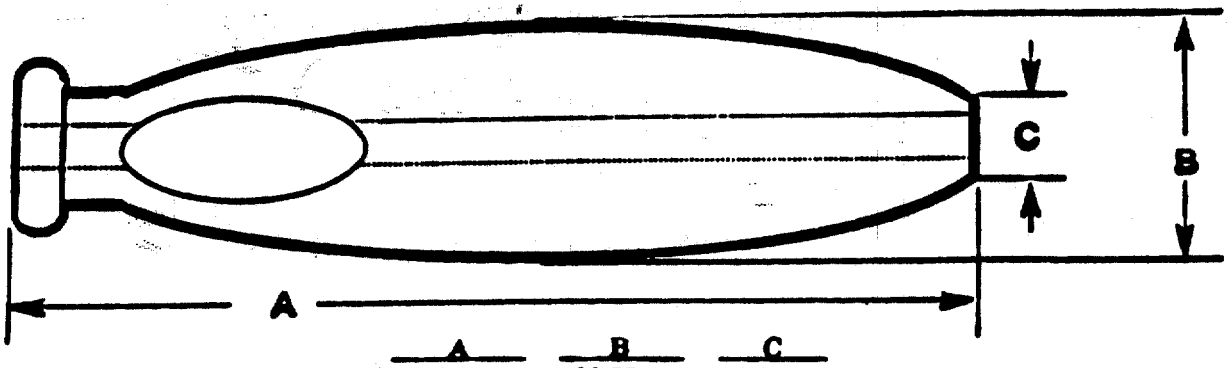

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MEDIUM	125.50 mm	33.50 mm	14.75 mm
LARGE	133.75 mm	41.70 mm	15.75 mm

PATENT PENDING

(b) (4) Medical Implant Grade Product Line

(b) (4) Medical Grade Silicones Testing

(b) (4) Medical Grade Silicones Testing

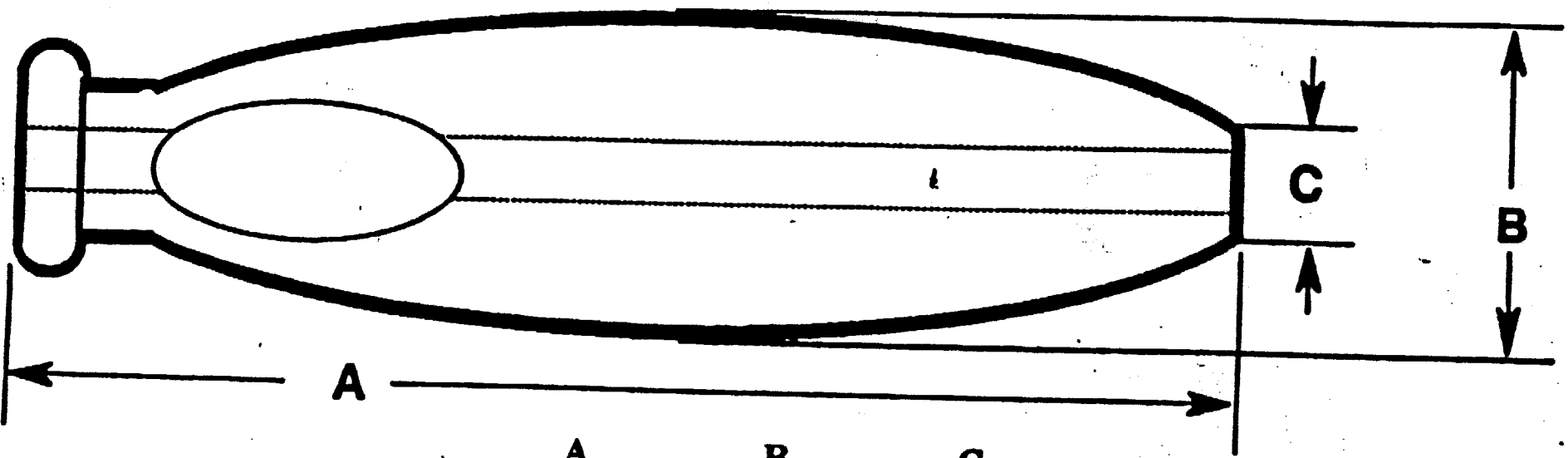
(b) (4) Medical Grade Silicones Testing

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

MEDIUM



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PATENT PENDING

NOMINAL VALUES

Bioteque America Inc.

Medical Products
Design & Development
Prototypes to Production

PREMARKET NOTIFICATION
510(k) STATEMENT
(AS REQUIRED BY 21 CFR 807.93)

I certify that, in my capacity as President of Bioteque America, Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including and adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information as defined in 21 CFR 20.61.

Denis P. Dorsey

5/25/95

K920633/E

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

103

Bioteque America Inc.

Medical Products
Design & Development
Prototypes to Production

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(AS REQUIRED BY 21 CFR 807.87(j))

I certify that, in my capacity as President of Bioteque America, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that not material fact has been omitted.

Denis P. Dorsey

5/25/95

K920633/E

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

104

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 1995

Mr. Dennis Dorsey
President
Bioteque America, Inc.
340 East Maple Avenue, Suite 102
Langhorne, Pennsylvania 19047

Re: K920633/E
Nichols Flexible Silicone Pessary
Dated: January 31, 1995
Received: February 3, 1995

Dear Mr. Dorsey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We still cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following additional information:

Device Description & Equivalence Comparison

1. The two predicate devices you cite (the Milex Gelhorn Pessary and the V. Mueller Counsellor Vaginal Mould) are quite different from each other in indication for use, function, shape, size and materials. Your device, the Nichols Pessary, is more like the Counsellor Vaginal Mould in terms of shape and size. However, your indication statements are more like those of the Gelhorn Pessary.

   a. Because your device design is quite similar to that of the Counsellor Vaginal Mould, you may submit labeling changes per that device (i.e., the Counsellor Vaginal Mould). No additional clinical data will be needed.

   b. If you wish to indicate the device like the Gelhorn Pessary, you will need clinical data to show that your device will perform comparably to the Gelhorn pessary for its indications.

Materials

2. Dow Corning has released a statement that their silicone elastomers should not be used in device applications "related to reproduction, contraception or obstetrics." Because a pessary will remain within the vagina for several months at a time, we believe your device may fall into this category. Either (1) provide us with a letter from Dow Corning stating that the company is aware of the intended use of your device and will supply their silicone to you for device manufacture, or (2) find an alternate material supplier and resubmit the material specifications and biocompatibility information for the new material.

105

Manufacturing Process

3. Please identify any additional chemicals used in the manufacturing process for this device (e.g., mold-releasing or mold-cleaning agents, etc.) and provide the chemical composition of these agents.

4. Please describe the quality assurance testing procedures completed during the manufacturing process, particularly with respect to dimensions and physical properties. Provide a detailed description of the protocols for each test, identifying the test specifications (including standard deviations), and the acceptable quality level (AQL). Also, provide a flow chart identifying when in-process and final release testing is done.

Material Toxicity

5. If additional chemicals are used in any of the manufacturing process (see above), biocompatibility testing should be performed on the final, sterilized device. Please include testing protocols and results.

   Biocompatibility information will also be needed if an alternate material is selected for device fabrication.

Labeling

6. Please provide a copy of your revised labels, labeling and advertisements to describe the device, the intended uses and directions for use.

7. Please delete the word "marked" from indication of use. In medical literature, vaginal prolapse is described in degrees.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

The requested information should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If the information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Mridulika Virmani, Ph.D., at (301) 594-1180. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Colin M. Pollard

Colin M. Pollard
Chief, Obstetrics/Gynecology Devices Branch
Division of Reproductive, Abdominal, Ear,
Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

107

Mr. Dennis Dorsey
President
Bioteque America, Inc.
340 East Maple Avenue, Suite 102
Langhorne, Pennsylvania 19047

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Dated: January 31, 1995
Received: February 3, 1995

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108

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109

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Sincerely yours,

/S/

Colin M. Pollard
Chief, Obstetrics/Gynecology Devices Branch
Division of Reproductive, Abdominal, Ear,
Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-470 Division
D.O.

MSVirmani
C:\WP51\FILES\510k\K920633E.AI
Draft:4/20/95:ens
Redraft: 5/03/95:slj
Redraft: 5/04/95:slj
Final: 5/04/95:slj

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ 470	Virmani	5/4/95						
HFZ 470	Pollard	5/5/95						

Public Health Service

Memorandum

Date

From REVIEWER(S) - NAME(S) Mridulika Virmani

Subject 510(k) NOTIFICATION K920633/S5

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:

_____

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

_____

REVIEW: Colin M Pollard (BRANCH CHIEF) OGDB (BRANCH CODE) 5/5/95 (DATE) FMP

FINAL REVIEW: _____ (DIVISION DIRECTOR) (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

OBGD

K920633

Reviewer: *Mridulika Virmani, Ph.D.*
Chemist

Division/Branch: DRAERD/ADOU/OGDB
(HFZ-470)

Proprietary Trade Name: Pessary Flexible Silicon Nichols

Common Name: Pessary

Product to which compared: Counsellor Type Vaginal Stent (V. Mueller Co.)

Applicant: Bioteque America, Inc.
340 E. Maple Ave., Suite 102
Langhorne, PA 19047

Contact: Mr. Denis Dorsey
Phone: 215-750-8071

DEVICE DESCRIPTION

1. *Intended Use:*

This device is an intravaginal obturator/pessary, intended to support the vaginal vault. This device is indicated for the correction of marked prolapse or procidentia. Alternatively, the device may be used in maintaining vaginal diameter and caliber of a patient who has sustained construction of a neovagina.

The device is removed, cleaned , and re-inserted by the patient from time to time, as per physician instructions. The device is not provided sterile or required to be sterile, but is intended for use only by a single patient, and cleaning periodically is important.

2. *Physical Description:*

	YES	NO
• 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 single use?	___	✓
• Is the device home use?	✓	___
• Is the device for prescription?	✓	___
• Does the device contain a drug or biological product as a component?	___	✓
• Is this device a kit?	___	✓

112

Provide a brief overview of the device, its design, principle of operation, and functional/performance characteristics.

The company has identified two predicate devices for the Pessary Flexible Silicone Nichols one is Milex's Gellhorn Pessary, and other is the Counsellor mold manufactured by the V. Mueller. The Gellhorn pessary is quite different in shape, size and indication of use than the Counsellor mold. The only similarity in Gellhorn pessary and Bioteque device is that both are made of silicone and fit intravaginally. The subject device is quite similar to Counsellor mold in shape, size and configuration, but the intended use are quite different. The Counsellor mold is used as a stent to maintain the vagina in a reasonable open state and retard scarring while healing from vaginal plastic procedures and the subject device is used to reduce the genital prolapse.

A figure of predicate device is shown in a catalog, the original Mueller's product called the Counsellor is out of business since 1980. The predicate device was made of polyethylene. It was soft, and flexible. The subject device is made of silicone and resembles to predicate in shape and size. The Bioteque pessary is referred as intravaginal obturator/pessary.

(b) (4)

REVIEW ANALYSIS

SE comparison

The gellhorn pessary identified and compared in the submission as predicate is quite different in shape ,size and configuration than that of the subject device.

The other predicate device is identified as the V.Mueller's Counsellor Vaginal Mold, a hollow molded polyethylene, vented at either end, with a flat indentation on either side. Diameter, 1 3/9", and overall length 4 1/2". This device is used after vaginal surgery to distant the vaginal canal during the post-operative healing process to prevent unwanted contraction of the scar. The vaginal stent is fitted and inserted by the physician and remains in place for up to several days. This Counsellor mold is similar to the bioteque's pessary in shape, size and design, but the indication of use is quite different for this device than that of subject device.

113

The two predicate devices are quite different in indication for use, function, shape,size and materials. The subject device is more like the Counsellor stent. Company should identify which of these two predicate is actual predicate device for subject device.

The Gellhorn pessary, which has a wide base to anchor it in the vagina, this device is a long cylinder whit a tapered distal end. With weakening and dilation of the levator muscles, will this device remain in its proper position without an external retainer. Sponsor should submit clinical data to support the validity of this device of its ability to effectively maintain the prolapsed used in its proper anatomical position (the Gellhorn has a wide base to anchor itself in the vagina).

If sponsor decides to use Counsellor as predicate device along with same indication of use as for Counsellor, he should provide the supporting documentation and new indication of use (similar to Counsellor's indication for use) for the subject device.

Materials

Material used for this device is Dow Corning Silastic Q7-4840. The use of this material has been discussed with Don Marlow of the Division of Mechanics and Materials Science at OST, CDRH point person for Dow corning silicone elastomers.

Dow Corning has released a statement that their silicone elastomers should not be used in device applications "related to reproduction, contraception or obstetrics." Because a pessary will remain within the vagina for several months at a time, we believe your device falls into this category. Either (1) provide us with a letter from Dow Corning stating that the company is aware of the intended use of your device, and allowing the use of their material for your application, or (2) find an alternate material supplier, and resubmit the material specifications and biocompatibility information for the new material.

Manufacturing Process

(b) (4)

[redacted]

Toxicity

The sponsor has provided appropriate biocompatibility information from Dow Corning. If, however, additional chemicals are used in the manufacturing process, biocompatibility testing is needed for the final finished device.

If additional chemicals are used in any of the manufacturing process (see

above), biocompatibility testing must be performed on the final, sterilized device. Please include testing protocols and results.

Biocompatibility information will also be needed if an alternate material is selected for device fabrication.

Packing

Each pessary will be packaged in a poly bag. A complete set of physician and patient instructions will be included with each device.

Labelling

The insertion and removal instructions are provided for the physician and patient. The cleaning instructions are also provided for the patients. The patient follow up instructions are provided and adequate.

The indication of use is same as for Gellhorn pessary. The indication for use is quite different for Mueller's Counsellor vaginal mold. For this device appropriate indication for use and proper supporting evidence for this indication for use is needed.

From indication of use, delete the word "marked" from prolapse. In medical literature the vaginal prolapse is described in degrees.

For the review of this device I have consulted Dr. Williams, and his review is attached.

REVIEWER RECOMMENDATION

Additional information is required.

Mridulika Virmani 4/20/95
Mridulika Virmani, Ph.D. Date

Colin M Pollard 5/5/95
Colin M. Pollard Date
Chief, Ob/Gyn Devices Branch

/V/ Concur
/ / Do Not Concur

Comments:

To: Mridu Virmani, Ph.D.
From: Eugene W. Williams, Jr., M.D.
Subject: K920633/S5 Pessary Flexible Silicone Nichols
Date: April 18, 1995

Medical Review:

(b) (4)

[redacted]

11/9

Conclusion:

(b) (4)

[redacted]

Eugene W. Williams, Jr., M.D.
Medical Officer

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)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 14, 1995

BIOTEQUE AMERICA, INC.
340 E. MAPLE AVENUE
SUITE 102
LANGHORNE, PA 19047
ATTN: DENNIS DORSEY

510(k) Number: K920633
Product: PESSARY FLEXIBLE SILICONE NICHOLS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above 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.

The Safe Medical Devices Act of 1990, 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. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at 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

118

K920633/S 5

Bioteque America Inc.

DUPLICATE

Medical Products
Design & Development
Prototypes to Production

1/31/95

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HZF-401)
1390 Piccard Drive
Rockville, Maryland 20850

Attention: Document Mail Clerk

RE: K920633
Proprietary Name: PESSARY FLEXIBLE SILICONE NICHOLS

With reference to our December 1994 telephone conversation, I have been fortunate to receive from David H. Nichols, MD. (the innovator of the PESSARY FLEXIBLE SILICONE NICHOLS) the enclosed material to substantiate the use of this device as a pessary. Please note that Dr. Nichols refers to this device as an intravaginal obturator/pessary. (see letter by Dr. Nichols dated 1/24/95). Also please refer to the letter from William Merz to Dr. Nichols of 8/11/80 that clearly mentions the Counsellor that Dr. Nichols, at one time, was able to purchase from the V. Mueller Company.

More importantly, the letter dated 1/20/94 describes a predicate device called the Counsellor. Unfortunately, the Counsellor is no longer manufactured by the V. Mueller. I believe they have gone out of business as the result of V. Mueller's death. To be more direct in response to your questions of December and referencing Figure 21.4 of our 510K submission, the following questions were asked by Dr. Vermani of the FDA. Our responses to the questions follow.

#1 Where did the Figure 21.4 come from?

At this time, Bioteque can not find the complete article. However, our device, the PESSARY FLEXIBLE SILICONE NICHOLS, is shown on page 211 of the V. Mueller catalog. The Figure 21.4 is an artist's conception of the original Mueller product called the Counseller.

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

1/9

#2 How was this device used and why did you select the shape?

The device is used as an obturator/pessary as described in Dr. Nichols' letter of 1/24/95.

#3 What was the name of this predicate device?

The original device was called a Counseller and manufactured by V. Mueller approximately 15 years ago.

#4. What was the material used in the original device?

The original device was called the Counseller and was made of polyethylene. According to Dr. Nichols, the Counseller was flexible and relatively soft.

#5. How does the Nichols Pessary compare to the device of Figure 21.4?

With Dr. Nichols' assistance, the PESSARY FLEXIBLE SILICONE NICHOLS was modeled to resemble the original Counseller in every respect except the material. The material selected was silicone as opposed to polyethylene. Its length, shape, flexibility, stem, and flat indentations are identical (or as close as Dr. Nichols could recall).

Sincerely,

Denis Dorsey

President, Bioteque America, Inc.

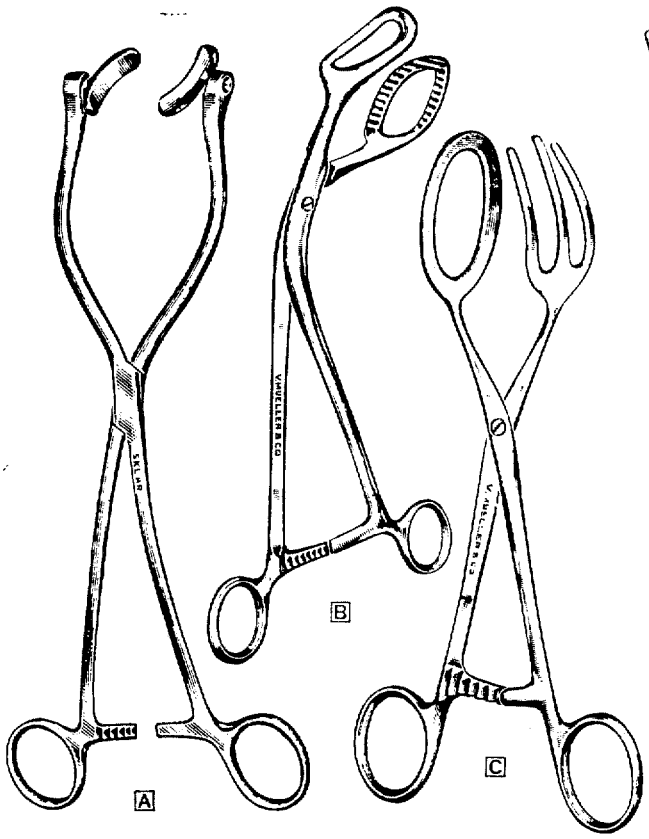
Enclosures

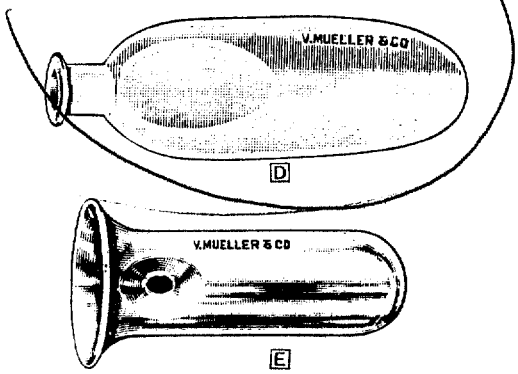
PS. Bioteque has included a sample of the PESSARY FLEXIBLE SILICONE NICHOLS for your review. Please compare this device with the Figure 21.4 and Figure D of the V. Mueller catalog.

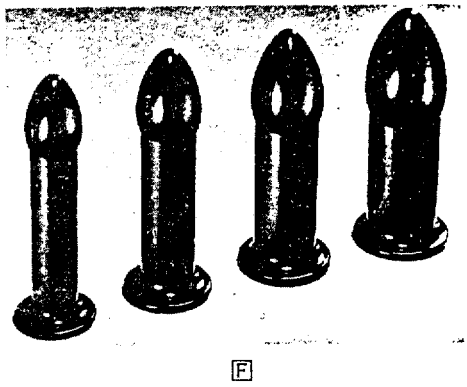
(b) (4) Letter dated 1/24/95 to Bioteque America Inc.

(b) (4) Letter dated 1/20/95 to Bioteque America Inc.

(b) (4)







UTERINE ELEVATING FORCEPS—VAGINAL DILATORS, MOULDS

A **GL-3025** BUXTON Uterine Clamp. With swivel jaws. Length, 9¾ inches. Stainless steel.

B **GL-3010** SOMERS Uterine Elevating Forceps. Curved. Jaws are fenestrated and serrated, for grasping the fundus of the uterus. Screw lock. Length, 9 inches. Stainless steel.

C **GL-3020** BARRETT-ALLEN Uterine Elevating Forceps. With one blade blunt and three-pronged, and one round fenestrated blade, both slightly curved. Screw lock. Length, 8 inches. Satin finish stainless steel.

D **GL-3630** COUNSELLOR Vaginal Mould. Hollow, moulded polyethylene, vented at either end, with a flat indentation on either side. Diameter, 1⅜", overall length, 4½". (Cold sterilize only.)

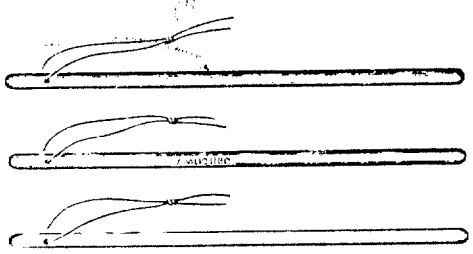
E **GL-3650** SIMS Vaginal Plug. Glass, with indentation to aid retention. Available in diameters of ⅞", 1", 1⅛", 1¼", 1⅜", and 1½". Please specify sizes.

F **GL-3660** YOUNG Vaginal Dilator Set. Bakelite, with closed tip, for treatment of dyspareunia and stenosis. Set of four sizes: No. 1½ (3" x ¾"); No. 2 (3¼" x $\frac{15}{16}$"); No. 3 (3½" x ¾"); No. 4 (3⅞" x $\frac{15}{16}$").

G **GL-3700** Laminaria Tents. For gradual dilatation of the cervix. Ten per package, gamma ray sterilized. 4 mm. diameter, small.

GL-3701 Same, but 7 mm. diameter, medium.

GL-3702 Same, but 10 mm. diameter, large.



AMBULATORY GYNECOLOGY

SECOND EDITION

Edited by

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Visiting Professor of Obstetrics, Gynecology, and Reproductive Biology
Harvard Medical School
Chief of Pelvic Surgery
Vincent Memorial Gynecologic Service
Massachusetts General Hospital
Boston, Massachusetts

Patrick J. Sweeney, MD, PhD
Professor of Obstetrics and Gynecology
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Women and Infants Hospital of Rhode Island
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CIP

This paper meets the requirements of ANSI/NISO 239.48-1992 (Permanence of Paper).

The authors and publisher have exerted every effort to ensure that drug selection and dosage set forth in this text are in accord with current recommendations and practice at the time of publication. However, in view of ongoing research, changes in government regulations, and the constant flow of information relating to drug therapy and drug reactions, the reader is urged to check the package insert for each drug for any change in indications and dosage and for added warnings and precautions. This is particularly important when the recommended agent is a new or infrequently employed drug.

Ambulatory Gynecology, Second Edition,
edited by David H. Nichols and Patrick J. Sweeney.
J. B. Lippincott Company, Philadelphia, © 1995.

20

The Vaginal Pessary

David H. Nichols and Peter Julian

USES OF A VAGINAL PESSARY

A properly fitted pessary can provide support for dropped, sagging, or prolapsed pelvic tissues in a symptomatic patient who cannot yet undergo surgery; hold in anteversion a symptomatic retroverted uterus; or restore temporarily a defective vaginal depth and the proper angle of the vaginouterine axis in a patient experiencing habitual abortion. In a patient with a mild genital prolapse or uterine retroversion in association with a backache, the use of a properly fitted vaginal pessary may indicate the amount of relief that can be expected from restorative surgery. It may be used as a test for the results one might anticipate from surgery for urinary incontinence and may be helpful after an unsuccessful prolapse repair by providing a window for emotional, physical, and social spacing before another surgical repair experience.[1]

The patient who wears a pessary must be regularly examined, the pessary removed and cleaned, and the vagina inspected for infection or ulceration. If the latter are found, the pessary is temporarily removed and an intravaginal sulfa cream prescribed in addition to a course of intravaginal estrogen. When the vagina has healed, the pessary is replaced.

Active pelvic inflammation contraindicates the use of a pessary; as a foreign body, it increases pelvic congestion and discomfort. Fixed retroversion of the uterus and pain after insertion are also contraindications to the use of a pessary.

The patient and her family should understand that a pessary is often a temporary treatment (unless life expectancy is shortened) because the patient may demonstrate vaginal stretching and coincident levator atrophy or neuromuscular disability over a long period of time, requiring placement with a pessary of larger size. Ultimately, such a patient is no longer be able to retain a pessary.

Diagnosis of Backache and Pelvic Pressure

Most multiparas and a few nulliparas have some degree of genital relaxation, and many have coincident symptomatic low backache. The gynecologist must decide whether such a backache is the result

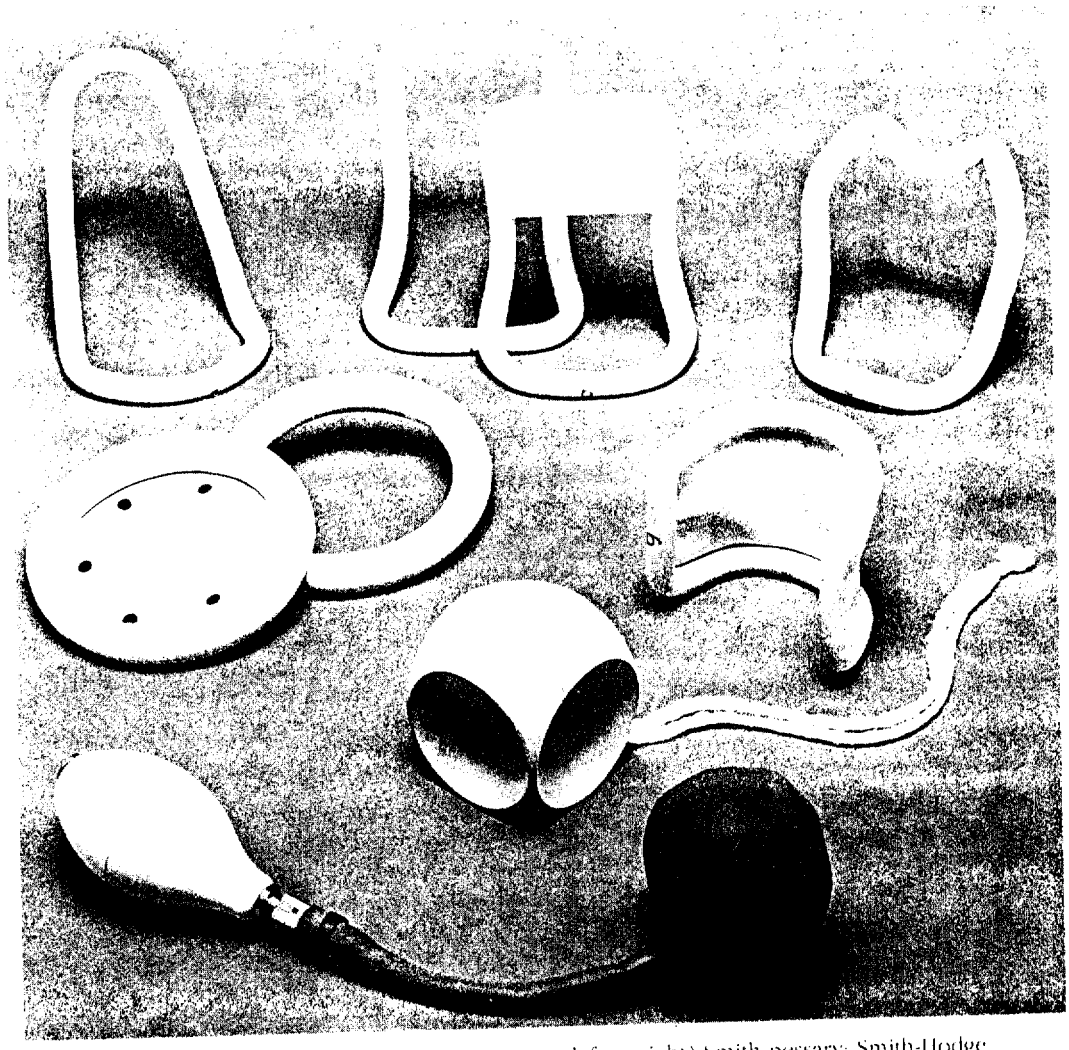


Figure 20–1. Commonly used pessaries. (*Top row*, left to right) Smith pessary; Smith-Hodge pessaries, with and without crossbard; Risser pessary. (*Middle row*) Ring pessaries (*left*); Gehrung pessary for cystocele (*right*). (*Bottom row*) Inflatable pessary and Bee-Cell pessary. (Courtesy Milex Products, Inc., 5915 Northwest Highway, Chicago, Illinois 60631)

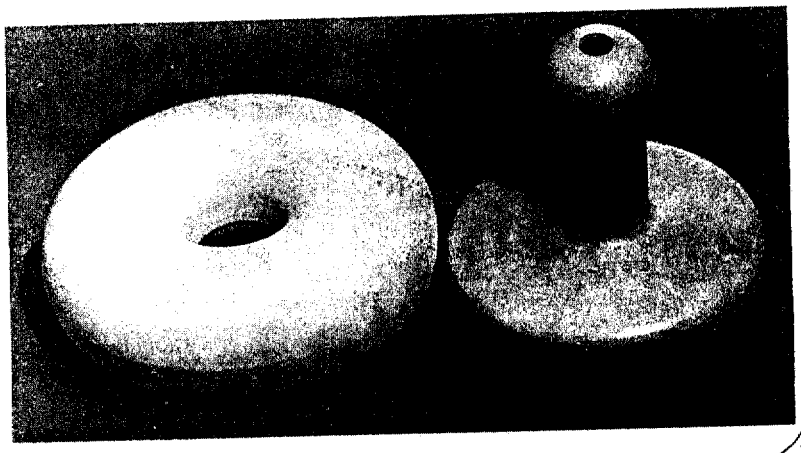


Figure 20–2. The hollow plastic donut pessary is shown on the left, and the flexible silicone Gellhorn pessary (with knob) is seen on the right. Each is available in an assortment of sizes (Courtesy Bioteque America, Inc., 417 Glendale Road, Wilbraham, MA 01095.)

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 04, 1995

BIOTEQUE AMERICA, INC.
340 E. MAPLE AVENUE
SUITE 102
LANGHORNE, PA 19047
ATTN: DENNIS DORSEY

510(k) Number: K920633
Product: PESSARY FLEXIBLE SILICONE NICHOLS

Extended Until: 04-FEB-95

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at 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

Bioteque America Inc.

Medical Products
Design & Development
Prototypes to Production

12/22/94

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

RE: K-920633 Pessary Flexible Silicone Nichols

I am requesting an extension of time to gather additional information for the reviewers of this submission. Your immediate attention to this matter will be greatly appreciated.

Sincerely,

Denis P. Dorsey

Bioteque America, Inc.

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 01, 1994

BIOTEQUE AMERICA, INC.
340 E. MAPLE AVENUE
SUITE 102
LANGHORNE, PA 19047
ATTN: DENNIS DORSEY

510(k) Number: K920633
Product: PESSARY FLEXIBLE SILICONE NICHOLS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

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

Sincerely yours,

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

131

Bioteque America Inc.

Medical Products — Design & Development Prototypes to Production

FAX MESSAGE

TO: COLIN POLLARD FOOD & DRUG ADMINISTRATION
FROM: DENIS DORSEY BIOTEQUE AMERICA, INC.
DATE: 12/1/94

RE: K920633 - PESSARY FLEXIBLE SILICONE NICHOLS

UPON RECEIPT OF THIS FAX, PLEASE BE ADVISED THAT MR. JAMES DORSEY IS NO LONGER THE POINT OF CONTACT FOR THIS SUBMISSION. FROM THIS DATE, 12/1/94, I (DENIS DORSEY) WILL BE THE POINT OF CONTACT FOR THIS 510K SUBMISSION.

SINCERELY,

DENIS DORSEY

Monday

340 East Maple Avenue • Suite 102 • Langhorne, PA 19047 • TEL (215) 750-8071 • FAX (215) 750-8073

DIVISION OF REPRODUCTIVE, ABDOMINAL, EAR, NOSE AND THROAT AND RADIOLOGICAL DEVICES

MEMORANDUM OF TELEPHONE CONVERSATION

BETWEEN: Dennis Dorsey Date: December 13, 1994

AND: Colin M. Pollard and Mridulika Virmani

TITLE: _____

COMPANY: Bioteque America, Inc.

PHONE NUMBER: 215-750-8017

FAX NUMBER: _____
(if applicable)

DOCUMENT NUMBER: K920633 /S4
(if applicable)

SUMMARY:

We returned the call from Mr.Dorsey. We talked about above mentioned 510k submission. He should provide the component materials for this device. Any additives or mold releasing agents used in the manufacturing process. If he has used any other material besides Dow Corning's Silastic(R) Q7-4840, he should provide biocompatibility tests on the final finished product as per tripartite guidelines.

We have asked him to provide physical characteristics of the final finished product, and if possible a sample of the Nicholas pessary as well as of predicate pessary.

He would arrange a conference call between his consultant physician and Colin and me, to explain the reasoning of his device configuration. He will also provide the details of his manufacturing process.

Signed: Mridulika Virmani 12/14/94

Original to: File
Copy to: _____
_____

SLJ/RRG 11/20/92 Rev. 3/30/94

133

(b) (4)

(b) (4)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date

From REVIEWER(S) - NAME(S) Colin Pollard

Subject 510(k) NOTIFICATION K920633154

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. Per telecon – See memo.

_____ (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:

_____

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

_____

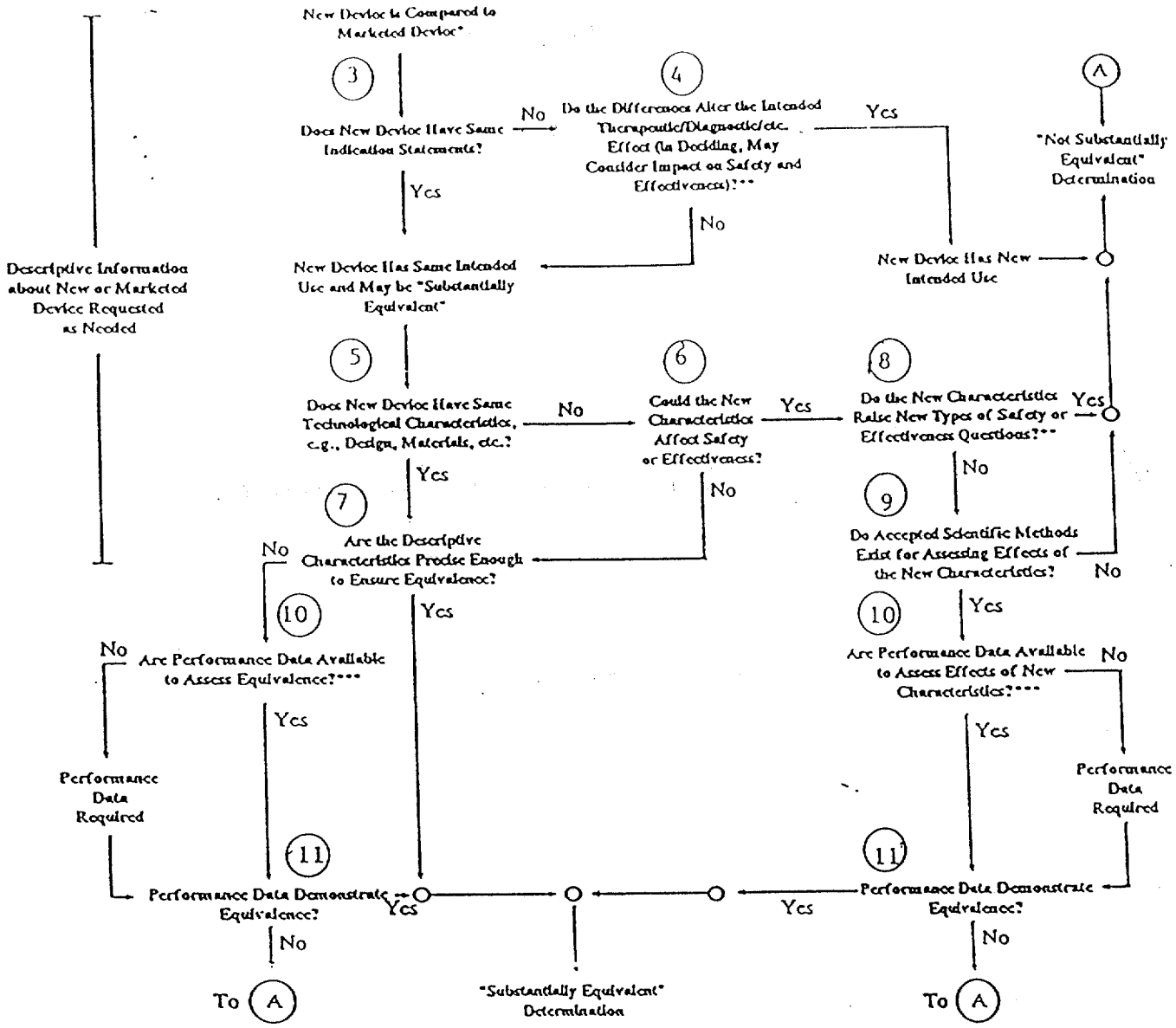
REVIEW: Colin M Pollard (BRANCH CHIEF) | OGDB (BRANCH CODE) | 11/30/94 (DATE)

FINAL REVIEW: _____ (DIVISION DIRECTOR) (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

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.

November 30, 1994

NOTE TO: The Record

FROM: Colin Pollard (HFZ-470)

SUBJECT: K920633
Nichols Flexible Silicone Pessary

(b) (4) [redacted]

I explained to Linda Wu at Bioteque that the 510(k) still had (b) (4) [redacted] She noted that James Dorsey was no longer with the firm, and that she would have Dennis Dorsey, president of Bioteque, call me back. I also asked for them to send a letter designating a new point of contact.

I explained that the 510(k) would return to hold status until Bioteque provide information responsive to the 3/9/94 AI letter.

Colin M Pollard

138

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

July 15, 1994

BIOTEQUE AMERICA, INC.
340 E. MAPLE AVENUE
SUITE 102
LANGHORNE, PA 19047
ATTN: DENNIS DORSEY

510(k) Number: K920633
Product: PESSARY FLEXIBLE SILICONE NICHOLS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above 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.

The Safe Medical Devices Act of 1990, 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. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at 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

179

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

Re: K920633
Attn: Mr. Colin M. Pollard
6/16/94

Dear Mr. Colin M. Pollard,

With reference to your letter dated March 10, 1994 and your recent telephone conversation on June 16, 1994. We are sorry for any confusion created by our earlier submissions and we wish to provide the following arrangement of additional information. We sincerely hope this information will complete the review of our submission.

This is to notify you of the intention of Bioteque America, Inc. to market the following device:

Classification Name: Pessary Vaginal.
Common Name: Pessary.
Proprietary Name: Pessary Flexible Silicone Nichols
Establishment Registration Number: 2529577

Classification: Pessary, Vaginal would most likely be reviewed by the FDA Obstetrics and Gynecology Device Panel. The classification number is 85HHW and listed as a class 2 device.

Performance Standards: Not applicable.

Label/Labeling/Promotional Material: Draft copies of the package labeling, drawings and labeled specimen are enclosed.

Substantial Equivalence: The Flexible Silicone Nichols pessary is similar in function and design and is equivalent in composition to the Milex Products, Inc. Silicone Gellhorn Pessary. Copies of the package, labeling/promotional material for the Milex product are enclosed.

We consider our intent to market our device as confidential information and request the FDA consider it as such. We have not disclosed the intent to market this device and have taken precautions to protect this confidentiality. Please do not hesitate to contact me at (215) 750-8071 if I can answer any questions in regards to this submission.

Sincerely,

James D. Dorsey

James D. Dorsey

413-599-1406

JDD/cs.
enclosures

140

Table of Contents

A. Comparison Table page 1

1. Device Description page 1

a. indication for use; page 1

b. design configuration; page 1

c. dimensions page 1

d. component materials page 1

e. physical properties page 1

f. packaging page 1

Engineering drawing - Bioteque Silicone Pessary page 2

Engineering drawing - Milex Silicone Pessary page 3

2. Component Materials; page 4

3. Toxicity Data; page 5

4. Manufacturing Process; page 19

5. Bioteque America, Inc. Silicone Pessary Device Labeling;

a. Product labeling Physician/Patient page 21

Single Patient Use Only (product label). page 21

Physician Instructions page 22

b. Fitting diagrams

Physician page 24

Patient page 25

Patient Instructions page 26

c. Adverse Effects page 26

Milex Product, Inc. Silicone Pessary Device Labeling page 27

Saftey and Effectiveness Statement page 29

Comparison Table

1) Device Description:	Flexible Silicone Nichols	Silicone Gellhorn Pessary
Company name:	Bioteque America, Inc.	Milex Products, Inc.
a. Indication for use:	for the correction of marked prolapse or procidentia.	for the correction of marked prolapse or procidentia.
Classification:	Pessary	Pessary
Class:	2	2
Classification #:	85HHW	85HHW
Regulation #:	884 3575	884 3575
b. Design Configuration:	Stem like, smooth flexible silicone.	Stem like, smooth flexible silicone.
c. Dimensions: see engineering drawings on page 2 and 3 for clear diagram.	Product # / Size O.D. S1675 37.5 mm M2550 41.7 mm L3375 47.7 mm	Product # / Size O.D. PGO38 38 mm PGO45 45 mm PGO51 51 mm
d. Component materials:	medical grade silicone DOW Q7-4840 A/B is a two part silicone elastomer. Enclosed you will find the specific chemical composition (MSDS section XII, on page 19) additional information is available by referencing the Dow Corning Medical Master File.	medical grade silicone
e. Physical Properties:	Flexible shore A43, with a smooth outer surface. see page 6 "Typical Properties"	Flexible shore A43, with a smooth outer surface.
f. Packaging:	1 pessary with instructions per poly bag.	1 pessary with instructions per poly bag.

(b) (4) Drawing

(b) (4) Drawing

Dow Corning
DOW CORNING Medical

SILASTIC® Q7-4840 A/B Medical Grade Liquid Silicone Rubber (LSR)

DESCRIPTION

SILASTIC® Q7-4840 A/B Medical Grade Liquid Silicone Rubber (LSR) is a two-part silicone elastomer specifically designed for liquid injection molding. Because of its consistency, it can also be utilized for crosshead and support extrusion applications. When the A and B components are mixed together in equal portions, the liquid will cure to a tough, rubbery elastomer via addition cure (platinum cure) chemistry.

Advantages of this product include:

- Solventless
- Translucent
- Pigmentable
- Two components mixed at a 1:1 ratio
- Long pot life at room temperature
- Rapid cure rate at elevated temperatures
- Medium-low durometer
- No volatile by-products
- Post-cure not required but can be used as an option to stabilize properties
- Complies with FDA regulations 21 CFR 177.2600, covering rubber articles intended for repeated food contact
- Liquid system permits high quality parts to be molded at rapid rates

APPLICATIONS

SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber is especially designed for manufacturing health care devices by either liquid injection molding or liquid extrusion. It can be utilized for bonding various silicone elastomer substrates. Some specific applications include:

- Precision molded parts
- Molded rubber stoppers and closures
- Encapsulated electronic parts
- O-rings
- Cloth coating
- Wire coating

The purchaser should thoroughly test products made in part or otherwise incorporating SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber to determine the acceptability of the product's performance in a specific application.

INSTRUCTIONS FOR USE

Blending

SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber is supplied as A and B components that must be combined in equal portions prior to use. Airless mixing, metering, and dispensing equipment is recommended for production operations. Information is available from Dow Corning on the suppliers of suitable pumping, mixing, and molding equipment. If hand mixing, a vacuum of 28 to 29 inches of mercury will sufficiently de-air the material in 20 to 30 minutes. At this reduced pressure, the material will normally rise above its original volume before collapsing.

Pot Life

After the A and B components are mixed, SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber will remain usable for 24 hours at room temperature. Refrigeration at lower temperatures -23°C (-10°F) significantly extends the usable life after mixing.

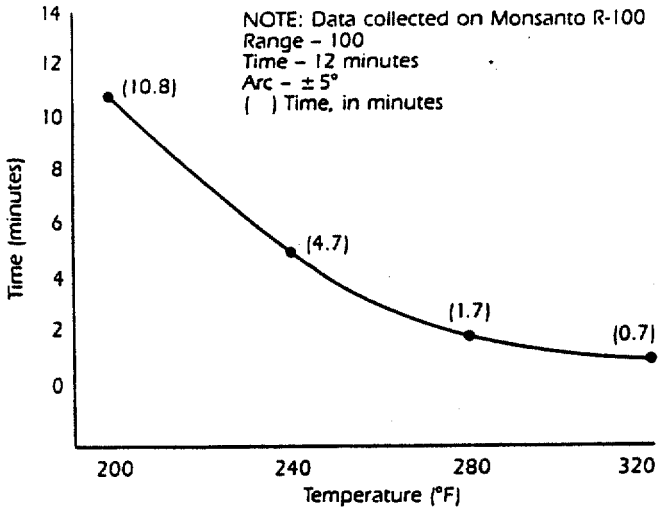
Vulcanization

Cure is initiated by the application of heat. Raising the temperature of the mass to 110°C (230°F) results in a very rapid cure to a tough elastomeric material. The premeasured catalyst gives the stock a fixed cure rate that can be measured on a Monsanto rheometer.

145

Mixing the two components in anything other than a 1:1 ratio will change the cure rate of the elastomer and the physical properties of the resulting part. This off-ratioing should be thoroughly evaluated by the user if it is to be considered as an option. The rate of cure may be varied by adjusting temperature as demonstrated in Figure I.

FIGURE I: Cure Rate[1] of SILASTIC® Q7-4840 A/B Medical Grade Liquid Silicone Rubber



[1]90% of torque at 12 minutes

Caution: The cure may be inhibited by traces of amines, sulfur, nitrogen oxide, organotin compounds, and carbon monoxide. Because organic rubbers often contain these substances, they should not come in contact with the uncured elastomer. For example, it has been demonstrated that extracts from certain latex gloves can inhibit the platinum cure chemistry. Catalyst residues from silicone Room Temperature Vulcanization (RTV) elastomers and peroxide-cured silicone elastomers may also inhibit the cure.

BIOCOMPATIBILITY

Biocompatibility tests, which meet or exceed current USP Class VI Plastics Tests, have been performed on vulcanized SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber and are shown in Table I. In addition, every production lot of elastomer is tested for levels of trace metals and for absence of cytopathic effects using tissue cell culture test (direct contact method).

TABLE I: Biocompatibility of SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber

Test	*Results*
Hemolysis, percent	<1
Pyrogenicity	Nonpyrogenic*
Intracutaneous Injection	Nonirritating*
Systemic Injection	Nontoxic*
Skin Sensitization	Nonsensitizing*
Intramuscular Implant	
10 days	Nonreactive*
30 days	Nonreactive*
90 days	Nonreactive*
Tissue Cell Culture	No Cytopathic Effect

*Based on comparison with defined USP negative controls.

SHIPPING LIMITATIONS

None.

STORAGE AND SHELF LIFE

The shelf life of unblended SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber A and B components is 6 months from date of shipment.

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications.

Property[1]	Result Q7-4840	Method ASTM	Method CTM[2]
As Supplied			
Color	Translucent		0176
Extrusion Rate[3], grams/minute	190		0364
As Cured			
Specific Gravity	1.13	D 792	0022
Durometer Hardness, Shore A, pts	43	D 2240	0099
Tensile Strength, psi	1300	D 412	0137A
Elongation, percent	500	D 412	0137A
Tear Strength, Die B, ppi	150	D 624	0159A
Tissue Culture	No CPE	–	0274
Metals, ppm		–	0571
Al	200 max.		
Na, Mg, Ca	100 max.		
P, Ti, Fe	50 max.		
Sb, Ge, Mn, Mo, Pb, Sn, Cr, Bi, V, Ag, Co, Ni, Cu, Zr, Ba, As, Zn, Se, Cd, Hg, Tl	10 max. each		

[1]All physical properties measured from 0.075-inch thick ASTM slab molded 5 minutes at 150 C (302 F) and equilibrated 24 hours at room temperature.

[2]Corporate Test Method (CTM) procedures correspond to standard ASTM tests and are available upon request.

[3]Test Parameters; 90 psi and 1/8-inch orifice.

Specification Writers: Please contact Dow Corning Corporation, Specification Dept., Midland, Michigan 48686-0994, before writing specifications on this product.

PACKAGING

SILASTIC® Q7-4840 Medical Grade Liquid Silicone Rubber is available in 80-lb (36.3-kg) and 900-lb (409-kg) kits, each with equal size containers of A and B components.

ORDERING

To order this product, call 1-800-248-2481, or contact our Sales Offices in Irvine, California; Buffalo Grove, Illinois; or Mount Olive, New Jersey. For global location information, please call.

PATENT POSITION

A composition prepared by mixing part A and part B of SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber is claimed in Dow Corning's U.S. Patent No. 4,162,243. Dow Corning intends to enforce this patent, but will offer licenses thereunder. If a license is needed, Dow Corning will ship the product in containers which bear a label license, and the invoice will include a statement of the royalty due. Alternatively, upon written request, Dow Corning will offer a license agreement at a comparable royalty rate under which the licensee may handle its own accounting of royalties due, regardless of the source of material.

SILASTIC® – This registered trademark is the brand name for Dow Corning's silicone elastomer products, materials and related products. Only Dow Corning may identify its products with the trademark SILASTIC®. The work is not a synonym for silicone elastomer and it is improper to use it without capitalization or to use it to identify another manufacturer's materials. Since it may not be used by others, the appearance of the word SILASTIC® on a medical product assures that it is of the highest quality and comes only from Dow Corning.

147

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

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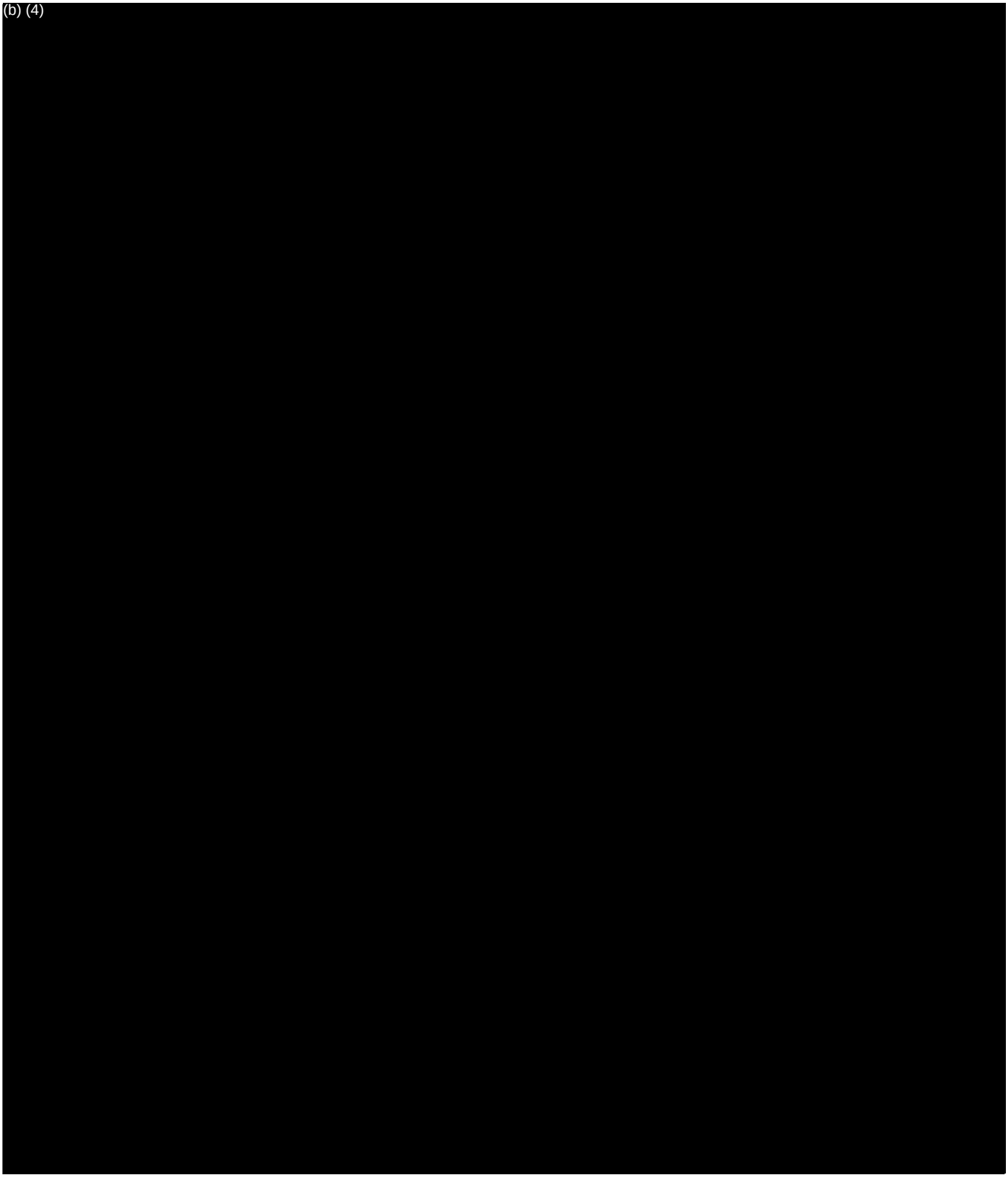
(b) (4) Material Safety Data Sheet

Manufacturing Process

COMPRESSION MOLDING

(b) (4)



160

(b) (4)

[redacted]

161

DISTRIBUTED BY:
BIO•AM™
Bioteque America, Inc.
340 East Maple Avenue
Suite 102
Langhorne, PA. 19047
Tel. (215) 750-8071
Fax (215) 750-8073

Bioteque America, Inc.

PESSARY FLEXIBLE SILICONE NICHOLS

The Flexible Silicone Nichols Pessary is available in three sizes.

For single patient use only.

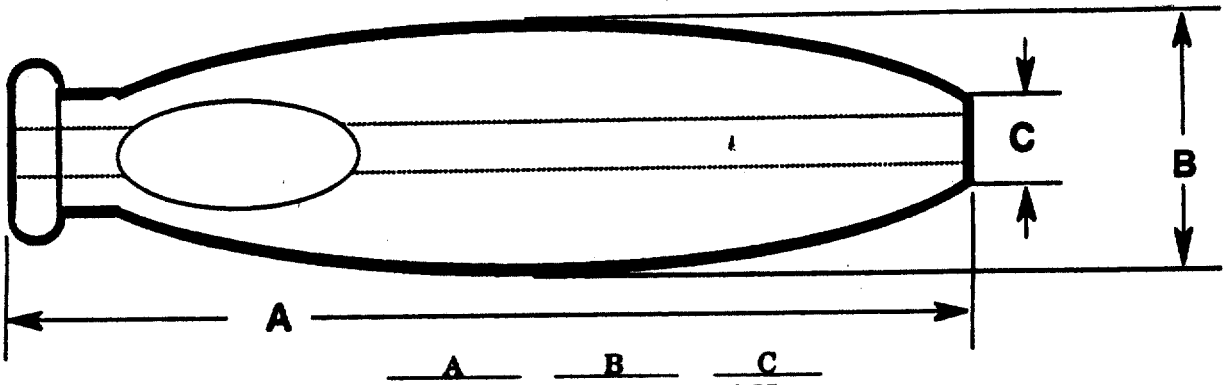
Product # S11675 (small), M1255 (medium), L133.75 (large).

CAUTION:
Federal law (U.S.A.) restricts this device to or on the order of a physician.

INDICATIONS :
For the correction of marked prolapse or prodentia.

CONTRAINDICATIONS :
Pessaries are contraindicated in acute genital tract infections or in the presence of pelvic infections or lacerations and in noncomplient patients.

MEDIUM



	A	B	C
SMALL	116.75 mm	30.75 mm	13.75 mm
MEDIUM	125.50 mm	33.50 mm	14.75 mm
LARGE	133.75 mm	41.70 mm	15.75 mm

PATENT PENDING

102

Physician Instructions

PROMOTIONAL MATERIAL

PESSARY FLEXIBLE
SILICONE NICHOLS (picture)

(see enclosed engineering drawings) B-012292

For Single Patient Use Only

CAUTION:

Federal law restricts this device to or on the order of a physician.

INDICATIONS:

For the correction of marked prolapse or procidentia.

CONTRAINDICATIONS:

Pessaries are contraindicated in acute genital tract infections or pelvic infections.

DIRECTIONS FOR USE:

Fitting requires a trial of sizes to determine the proper Pessary Flexible Silicone Nichols. (see promotional material)

#1. Perform a normal pelvic examination prior to the introduction or fitting of a pessary. The size selection is more or less trial and error, yet the pelvic exam helps to determine the selection of the appropriate size. *NOTE: The flexibility of the Pessary Flexible Silicone Nichols simplifies insertion and removal.*

#2. The Pessary Flexible Silicone Nichols should be inserted base (opposite the removal stem) first onto the introdus. After insertion, the stem should be in the downward position.

#3. The pessary should not dislodge by standing, sitting, squatting, or bearing down.

163

NOTE: The pessary should be large enough to do its designed function however, you do not want it to cause undue pressure or discomfort.

TO REMOVE:

#1. Gently pull the knob on the pessary to bring the pessary closer to the introdus and within fingers reach.

#2. Use fingers to open the labia for easy removal.

#3. Completely wash the pessary with a mild soap and warm water.

#4. Check the vagina for any evidence of pressure of sensitivity to the pessary. Also, question the patient about douching irritations and if there has been any improvement in her personal symptoms.

#5. It is necessary to check the fit of the pessary to be sure of the correct size for continued patient comfort and relief.

#6. Schedule follow-up visits to fit the needs of the individual patient.

SUGGESTED PATIENT FOLLOW-UP:

#1. Report any discomfort immediately.

#2. Return in 24 to 48 hours to make sure the patient is not allergic to the pessary.

#3. Patient should be instructed to remove the pessary every day or two for cleaning.

#4. Follow-up is then gradually lengthened to one to two month intervals.

These instructions courtesy of David H. Nichols, MD

Sizes Available: Small, Medium, and Large

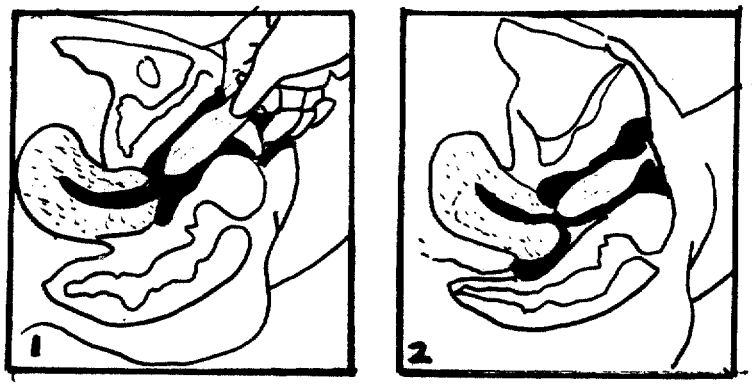
1604

Fitting Diagrams - Physician

Instruct the patient to report any discomfort. The patient should return in twenty four hours for first examination. The patient should be instructed to remove the pessary every day or two for cleaning (wash with mild soap and warm water then rinse before reinsertion). Have patient return in three days for second examination and then schedule monthly return visits.

During each visit the vagina should be checked for evidence of unnecessary presure or allergic reaction. Patient should be questioned concerning douching, discharge, disturbance of bowel function and urination.

1 **When inserting the pessary your pelvic muscles must be relaxed. With one hand spread the labia minora and with the other insert the blunt end of the well lubricated (use any water soluble gel) pessary into the vaginal cavity and gently make pressure, pushing the pessary into the vagina until it stops and the knob end is comfortably within the vagina.**



2 **After the pessary is within the vagina vault the pessary is it is rotated to its proper position, turned so that one flattened surface near the knob end will come to rest beneath the ureathra, and replaced more easily if you wear a supportive sanitary napkin when the pessary is in place.**

Fitting Diagrams and Instructions - Patient

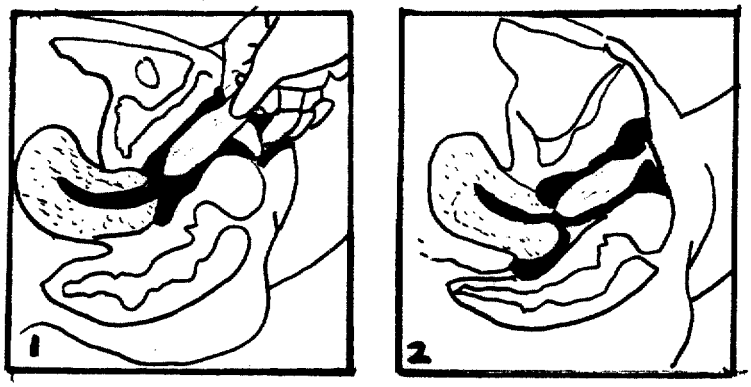
Patient Instructions for Pessary Wearers

To relieve the symptoms of your genital prolapse your physician has inserted a silicone vaginal support known as a pessary. When properly inserted it should be comfortable for you, to the extent that whenever standing or reclining you should be unaware or its presence.

Bowel and bladder habits should be unaffected by the pessary, or even improved while in place.

The pessary should be removed daily for cleaning (mild soap and warm water then rinse) and reinsertion. The pessary is inserted and removed as pictured below.

1 When inserting the pessary your pelvic muscles must be relaxed. With one hand spread the labia minora and with the other insert the blunt end of the well lubricated (use any water soluble gel) pessary into the vaginal cavity and gently make pressure, pushing the pessary into the vagina until it stops and the knob end is comfortably within the vagina.



2 After the pessary is within the vagina vault the pessary is it is rotated to its proper position, turned so that one flattened surface near the knob end will come to rest beneath the ureathra, (which is the external opening of the bladder) and replaced more easily if you wear a supportive sanitary napkin when the pessary is in place.

Patient Instructions - Adverse Effects

To obtain the maximum benefit from, and ensure the desired correction of your condition for which a pessary is indicated, your doctor needs your full cooperation.

Recommended follow-up for pessary wearers:

A. Report immediately any discomfort.
B. Call physician if pessary falls out.
C. Return within 24 hours for follow-up examination.
D. Return for second follow-up examination within three days.
E. Follow-up is then lengthened to one or two month intervals depending on the individual needs of the patient.

Adverse Effects:

Report any of the following symptoms to your physician immediately.

- Any change in the color or consistancy of your vaginal discharge.
- Any increase in amount of vaginal discharge.
- Any foul oder associated with vaginal discharge.
- Vaginal itching.

167

Milex Folding Pessary

gellhorn

Support for third degree prolapse/procidentia

MILEX code: PGEO + Size

CPT code: Procedure: 57160
Supplies: 99070

Caution: Federal Law restricts this device to sale by or on the order of a physician.

Indications: For effective support of third degree prolapse or procidentia.

Contraindication: Supportive pessaries are contraindicated in the presence of pelvic infections or lacerations. Since the gellhorn pessary is difficult for the patient to remove,it is also contraindicated in any sexually active patient.

There have not been problems in the past with allergic reaction. The rare case can usually be quickly discovered when the patient returns within 24 hours for the first follow-up examination.

ADVANTAGES OF MEDICAL GRADE SILICONE

1. Longer shelf life and use life.
2. Does not absorb odors or secretions.
3. Can be autoclaved, boiled or cold sterilized.
4. Non-allergic.

Patient should void before any pessary fitting.

Instructions for use:

1. The only method of determining the proper size gellhorn pessary is by trial and error. Perform a normal pelvic exam before insertion or fitting of any pessary. A first approximation of size can be made by using the width of your

1168

fingers to determine the approximate width of the vaginal vault. This will generally get you within a size of the proper pessary.

2. In some cases the pessary may be compressed between the thumb and forefinger. If necessary the entering edge can be coated with TRIMO-SAN or other suitable lubricant.

3. Use the fingers of the other hand to spread the labia, and guide the pessary into the vagina. It is frequently advisable to insert with the large disc portion turned parallel to the introitus. (Fig. I) After the disc is in the vaginal vault, it is rotated to Its proper position (see Figure 2).

Fig. 1. Pessary is inserted with the large disc, parallel to the introitus.

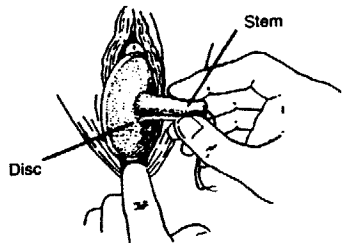
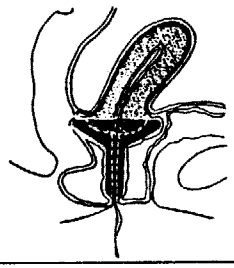


Fig. 2. Support of the uterus by the Gelllhorn, pessary.



Other types of pessaries available for third degree prolapse/procidentia are: **CUBE, INFLATO BALL, INFLATED DONUT and CLEAR PLASTIC GELLHORN.**

To remove:

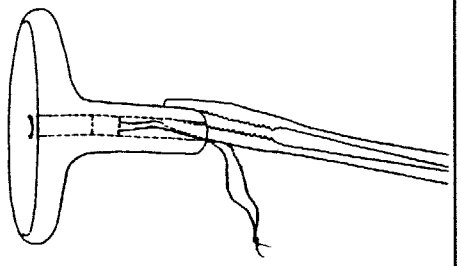
1. Gently pull on string to bring the disc portion of the pessary close to the introitus and within fingers' reach.

   a. If necessary, insert one blade of uterine dressing forceps into drainage opening of pessary, clamp the other blade gently to the outer, lower portion of the stem. (See Fig. 3)

   b. Pull gently until you can reach the disc portion of the pessary.

2. Use fingers to spread labia and fold the disc for easy removal.

Fig. 3.



3. Wash pessary with mild soap and warm water and rinse thoroughly.

4. Thoroughly rinse stem channel.

5. Do not assume that a replacement will always be the same size as before. Check the fitting to assure continued patient comfort and relief of symptoms. The user-life of a pessary is limited. Examine frequently for signs of deterioration.

6. Schedule frequent follow-up examinations to fit the needs of the individual patient.

DIRECTIONS FOR STERILIZING

1. AUTOCLAVE 15 LBS. (250°F) PRESSURE FOR 15 MINUTES.
2. BOIL FOR 15 MINUTES.
3. COLD STERILIZE.

Patient follow-up

- Report immediately any discomfort.
- Return within 24 hours for first examination.
- Return for second examination within 3 days.
- Patient should be asked to return at 4 weeks intervals.

During each visit the vagina should be carefully inspected for evidence of pressure or allergic reaction. Patient should be questioned concerning douching, discharge, disturbance of bowel function and urination. It may be necessary to fit another size or an entirely different shape folding pessary.

NOTE: Above schedule of follow-up examinations may be altered to fit the needs of the individual patient and physician.

TRIMO-SAN, a cleansing vaginal deodorant gel with a pH4, is frequently recommended for pessary wearers. Suggestion: Advise your patient Trimo-San is available at the prescription counter upon request (no Rx required).

(SEE PACKAGE INSERT FOR COMPLETE DIRECTIONS)

Flexible silicone pessaries are available in the following Disc Diameters: (Stem lengths uniform on all sizes.)

SIZE	DIAMETER		SIZE	DIAMETER	
(1)	1 1/2"	(38mm)	(6)	2 3/4"	(70mm)
(2)	1 3/4"	(45mm)	(7)	3"	(76mm)
(3)	2"	(51mm)	(8)	3 1/4"	(83mm)
(4)	2 1/4"	(57mm)	(9)	3 1/2"	(89mm)
(5)	2 1/2"	(64mm)			

DRAERD 510(k) Summary/Statement Certification

This document or its equivalent must be completed and included with each 510(k) submission.

I, Louis Dorsey (type/print name) as President (Title)
of Biotegue Am. Inc. (Company Name) certify that (check either 1 or 2):

☐ 1. This premarket notification contains a summary of safety and effectiveness information upon which an equivalence determination could be based. This summary does not contain any confidential information and is fully releasable. (NOTE: The summary must be provided as a separate section of the submission.)

☑ 2. Biotegue Am. Inc. (Company Name) will make available to interested persons upon request, the safety and effectiveness information in this premarket notification that is relevant to an assessment of substantial equivalence.

Signature Louis Dorsey

3/29/94
Date

1P

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 20, 1994

BIOTEQUE AMERICA, INC.
340 E. MAPLE AVENUE
SUITE 102
LANGHORNE, PA 19047
ATTN: DENNIS DORSEY

510(k) Number: K920633
Product: PESSARY FLEXIBLE SILICONE NICHOLS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

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

Sincerely yours,

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

510(K) ROUTE SLIP

510(k) NUMBER K920633 PANEL OB DIVISION DRAER BRANCH OGDB

TRADE NAME PESSARY FLEXIBLE SILICONE NICHOLS

COMMON NAME

PRODUCT CODE ___

APPLICANT BIOTEQUE AMERICA, INC.
SHORT NAME BIOTAMER
CONTACT DENNIS DORSEY
DIVISION
ADDRESS 340 E. MAPLE AVENUE
SUITE 102
LANGHORNE, PA 19047
PHONE NO. (215) 750-8071 FAX NO. (___) ___-____

MANUFACTURER BIOTEQUE AMERICA, INC. REGISTRATION NO. 2529577

DATE ON SUBMISSION 27-JAN-92 DATE DUE TO 510(K) STAFF 27-APR-92

DATE RECEIVED IN ODE 12-FEB-92 DATE DECISION DUE 12-MAY-92

DECISION __ DECISION DATE _____

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	29-MAY-92	29-MAY-92	27-AUG-92	14-AUG-92	
S002	15-JUL-93	24-AUG-93	07-NOV-93	22-NOV-93	09-MAR-94
S003	28-MAR-94	04-APR-94	18-JUN-94	03-JUL-94	20-JUN-94

CORRESPONDENCE	SENT	DUE BACK	
C003	09-MAR-94	08-APR-94	HOLD LETTER
C004	20-JUN-94	20-JUL-94	HOLD LETTER
C001	29-APR-92	29-MAY-92	HOLD LETTER
C002	14-AUG-92	13-SEP-92	HOLD LETTER

172

Memorandum

Date

From REVIEWER(S) - NAME(S) [redacted] Mridulika Virmani

Subject 510(k) NOTIFICATION K920633/S3

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. Telephone Hold.

_____ (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:

_____

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

_____

REVIEW: Colin M Pollard (BRANCH CHIEF) | OHDB (BRANCH CODE) | 6/16/94 (DATE)

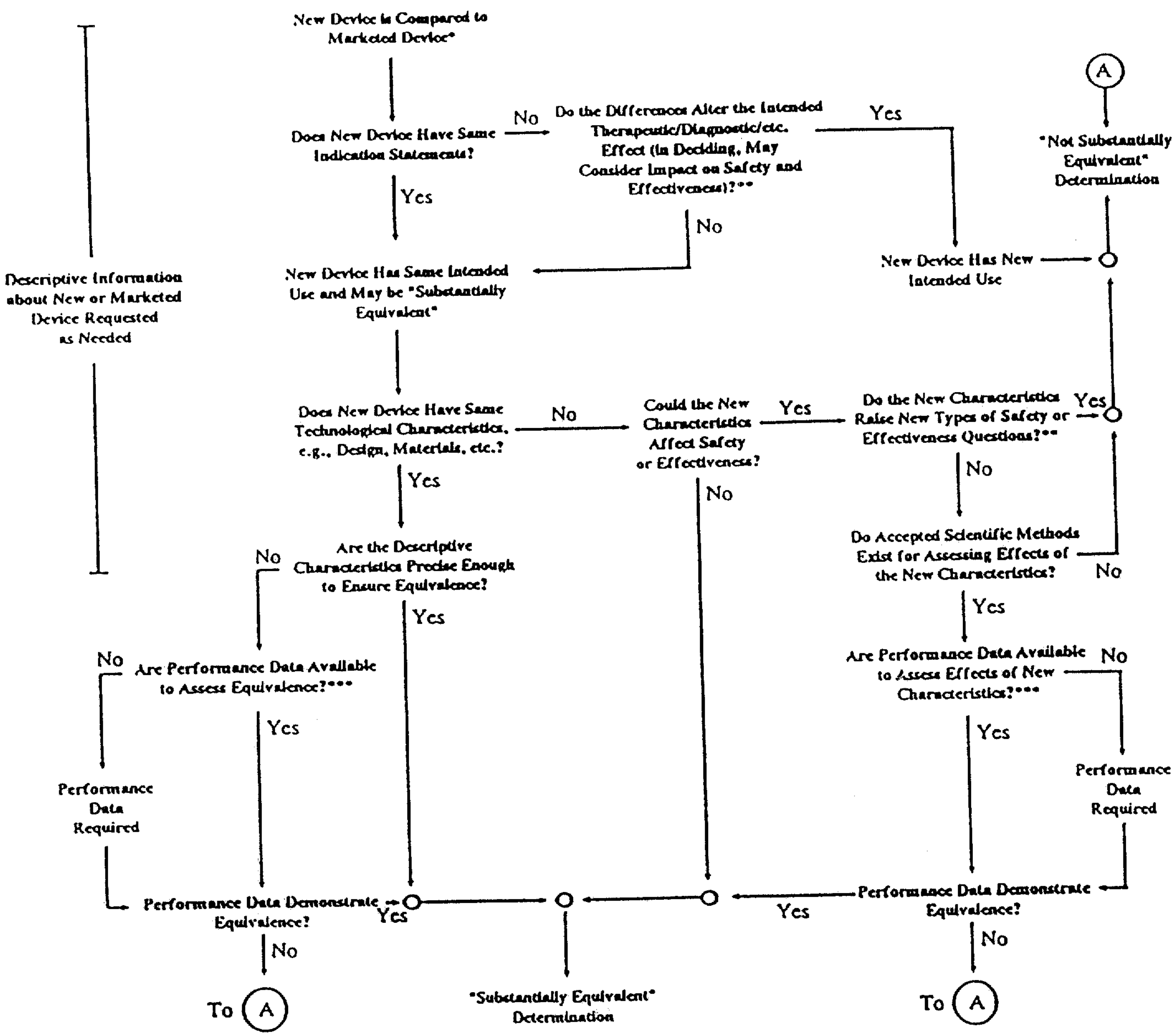
FINAL REVIEW: R Cathey for L Lin (DIVISION DIRECTOR) 6/17/94 (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

1/3

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.

DIVISION OF REPRODUCTIVE, ABDOMINAL, EAR, NOSE AND THROAT
AND RADIOLOGICAL DEVICES

MEMORANDUM OF TELEPHONE CONVERSATION

BETWEEN: Colin Pollard and Mridulika Virmani Date: 6/10/93

AND: Mr. Denis Dorsey

TITLE: President

COMPANY: Bioteque America Inc.

PHONE NUMBER: 215-750-8071

FAX NUMBER: _____
(if applicable)

DOCUMENT NUMBER: K920633/S3
(if applicable)

SUMMARY:

We called Mr. Dorsey and discussed all the questions mentioned in AI letter to him sent on 3-9-94. In his latest submission he did not response to majority of questions properly or completely. So we explained to him he has to send more data, and a descriptive answer to each and every question asked in the FDA letter of 3-09-94.

We would like to keep this document K920633/S3 on telephone hold, until we get all the answers.

Signed: Mridulika Virmani 6-13-94

Original to: K920633/S3
Copy to: _____
_____

SLJ/RRG 11/20/92 Rev. 3/30/94

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

April 05, 1994

BIOTEQUE AMERICA, INC.
51 RAINLILY ROAD
LEVITTOEN, PA 19056
ATTN: DENIS DORSEY

510(k) Number: K920633
Product: NICHOLS VAGINAL STENT

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above 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.

The Safe Medical Devices Act of 1990, 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. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at 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

176

Hold

MANUFACTURER'S STATEMENT OF SUBSTANTIAL EQUIVALENCE

(To be provided with 510(k) notifications for tier 1 devices)

RE: PESSARY FLEXIBLE SILICONE NICHOLS K920633/A

STATEMENT OF INDICATIONS FOR USE: for correction of a marked prolapse or procidentia

CLAIMS: NONE

This notification contains all of the information required by 21 CFR 807.87. A completed copy of the "DRAERD Premarket Notification 510(k) Reviewer's Screening Checklist" is attached.

The subject device conforms to the following voluntary and mandatory standards:

NONE

The subject device has the same technological characteristics as a legally marketed predicate device. Specifically, the features, specifications, materials, and mode of action are equivalent. If the subject device is a kit, all of the contents of the kit are either pre-Amendment devices or have been cleared for marketing through previous 510(k)s. The kit contains no drug or biologic product.

The above statements are accurate representations of this 510(k) premarket notification and of the device this firm intends to market. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted (21 CFR 807.87(j)).

MANUFACTURER: BIOTESQUE AMERICA, INC.
340 E MAPLE AVE
SUITE 102
LANGHORNE, PA 1904

OFFICIAL CORRESPONDENT: Denis P. Dorsey (signature)

DENIS P. DORSEY (printed name)

TITLE: PRESIDENT

DATE: 1/25/94

RECEIVED
MAR 31 10
FDA/CDRH/ODE/DMC

MANUFACTURER'S STATEMENT OF SUBSTANTIAL EQUIVALENCE

(To be provided with 510(k) notifications for tier 1 devices)

RE: PESSARY FLEXIBLE SILICONE NICHOLS K920633/A

STATEMENT OF INDICATIONS FOR USE: for correction of a marked prolapse or procidentia

CLAIMS: NONE

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The above statements are accurate representations of this 510(k) premarket notification and of the device this firm intends to market. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted (21 CFR 807.87(j)).

MANUFACTURER: BIOTESQUE AMERICA, INC. 340 E MAPLE AVE SUITE 102 LANGHORNE, PA 1904

OFFICIAL CORRESPONDENT: Denis P. Dorsey (signature)

DENIS P. DORSEY (printed name)

TITLE: PRESIDENT

DATE: 1/25/94

178

K920633/S3

March 28,1994

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HZF-401)
1390 Piccard Drive
Rockville, Maryland 20850

RE: 510 (k) Number: K920633/B

Re-submission to FDA inquiry dated 3/9/94

Attention: Document Mail Clerk

NOTICE #2: Change of K920633/B Name

FROM
NICHOLS VAGINAL STENT

TO
PESSARY FLEXIBLE SILICONE NICHOLS

1. Device Description and Comparison to a Legally Marketed Device

This is to notify you of the intentions of Bioteque America, Inc. to market the following device:

Classification Name: PESSARY, Vaginal
Classification Number: 85HHW
Common Name: PESSARY
Proprietary Name: PESSARY FLEXIBLE SILICONE NICHOLS

Establishment Registration Number: From form FDA 2891 - 2529577

Classification: The vaginal PESSARY would most likely be reviewed by the FDA's Obstetrics and Gynecology Device Panel. The classification number is 85HHW, the regulation number is 884.3575, and the device is listed as class II.

Performance Standards: Not applicable

Label, Labeling, Promotional Material, and Drawings: Draft copies are enclosed.

Substantial Equivalence: The Pessary Flexible Silicone Nichols is similar in function to the Gramm-Field Grafco Gellhorn Pessary, the Bioteque America, Inc. Silicone Gellhorn Pessary (K920187), and the Milex Gellhorn Pessary. The design of the Pessary Flexible Silicone Nichols is modified to increase the "stem" diameter and length while reducing the Gellhorn base ring to match the dimensions extended stem.

Material: The material composition is medical grade silicone Q7-4840 A/B by Dow Corning Medical that complies with FDA regulations 21 CFR 177.2600.

Packaging: The Pessary Flexible Silicone Nichols will be packaged individually in a sealed polybag with instructions inclosed. There will be 25 Pessary Flexible Silicone Nichols per box (maximum).

Bioteque America, Inc. considers the intentions to market this substantially equivalent device as company confidential information and therefore requests the FDA to act accordingly. We have not disclosed the intent to market this device to anyone and have taken all necessary precautions to protect this confidentially.

We also would appreciate the FDA's earliest attention to this 510(K) submission. Please do not hesitate to call Bioteque America, Inc. at 215 750-8071 or 8072 at your convenience with regards to any questions concerning this submission.

Sincerely,

Denis Dorsey

President, Bioteque America, Inc.

Enclosures

180

PROMOTIONAL MATERIAL

PESSARY FLEXIBLE
SILICONE NICHOLS (picture)

(see enclosed engineering drawings) B-012292

For Single Patient Use Only

CAUTION:

Federal law restricts this device to or on the order of a physician.

INDICATIONS:

For the correction of marked prolapse or procidentia.

CONTRAINDICATIONS:

Pessaries are contraindicated in acute genital tract infections or pelvic infections.

DIRECTIONS FOR USE:

Fitting requires a trial of sizes to determine the proper Pessary Flexible Silicone Nichols. (see promotional material)

#1. Perform a normal pelvic examination prior to the introduction or fitting of a pessary. The size selection is more or less trial and error, yet the pelvic exam helps to determine the selection of the appropriate size. *NOTE: The flexibility of the Pessary Flexible Silicone Nichols simplifies insertion and removal.*

#2. The Pessary Flexible Silicone Nichols should be inserted base (opposite the removal stem) first onto the introdus. After insertion, the stem should be in the downward position.

#3. The pessary should not dislodge by standing, sitting, squatting, or bearing down.

181

NOTE: The pessary should be large enough to do its designed function however, you do not want it to cause undue pressure or discomfort.

TO REMOVE:

#1. Gently pull the knob on the pessary to bring the pessary closer to the introdus and within fingers reach.

#2. Use fingers to open the labia for easy removal.

#3. Completely wash the pessary with a mild soap and warm water.

#4. Check the vagina for any evidence of pressure of sensitivity to the pessary. Also, question the patient about douching irritations and if there has been any improvement in her personal symptoms.

#5. It is necessary to check the fit of the pessary to be sure of the correct size for continued patient comfort and relief.

#6. Schedule follow-up visits to fit the needs of the individual patient.

SUGGESTED PATIENT FOLLOW-UP:

#1. Report any discomfort immediately.

#2. Return in 24 to 48 hours to make sure the patient is not allergic to the pessary.

#3. Patient should be instructed to remove the pessary every day or two for cleaning.

#4. Follow-up is then gradually lengthened to one to two month intervals.

These instructions courtesy of David H. Nichols, MD

Sizes Available: Small, Medium, and Large

DEVICE DESCRIPTION

a. indications for use; see enclosed promotional material

b. design configuration(s); see enclosed promotional material and engineering drawing

c. dimensions; see enclosed promotional material and engineering drawing

d. component material; the material composition is medical grade silicone Q7-4840 A/B by Dow Corning Medical that complies with FDA regulations 21 CFR 177.2600. (all Dow data is enclosed)

e. physical properties; the Pessary Flexible Silicone Nichols is made of flexible silicone (flex modulus is A 44), the surface is smooth identical to surface texture of a Gellhorn type pessary

f. compares to Milex Code 20 device (data sheet enclosed)

MILEX	BIOTEQUE NICHOLS PESSARY
L(SM) = 124 MM	L(SM) = 112.50MM
L(M) = 133MM	L(M) = 133.75MM
L(LG) = 141MM	L(LG) = 155.OOMM
DIA(SM) = 22MM	DIA(SM) = 37.50MM
DIA(M) = 26MM	DIA(M) = 41.70MM
DIA(LG) = 30MM	DIA(LG) = 47.7MM
MATERIAL - UNKNOWN	MATERIAL - DOW Q7-4840
FLEX - UNKNOWN	FLEX - A44

183

DISTRIBUTED BY:
BIO•AM™
Bioteque America, Inc.
340 East Maple Avenue
Langhorne, Pa 19047
Tel. (215) 750-8071
Fax (215) 750-8073

Bioteque America, Inc.

NICHOLS SILICONE PESSARY (Obturator-Type)

The Nichols Silicone Pessary (Obturator-Type) is available in three sizes. For single patient use only.

Product # NSPS (small), NSPM (medium), NSPL (large).

Caution:

Federal law (U.S.A.) restricts this device to or on the order of a physician.

Indications:

To support or distend the vaginal canal.

Contraindications:

Pessaries are contraindicated in acute genital tract infections or in the presence of pelvic infections or lacerations.

Instructions for the Physician:

Following the construction of a neovagina or any portion thereof, or following a vaginalplasty operation performed to enlarge a small vagina, or for relief of vaginismus it is usually desired to support or distend the vaginal canal with a device to prevent unwanted contraction of the scar or to relax the muscles that surround the vagina. Such an obturator should be simple, smooth surfaced, light in weight, capable of removal and insertion by the patient and affordable. It should be available in various sizes comparable to those of the erect penis. Since even a silicone obturator is a foreign body in the vagina, any vaginal secretions must route through the obturator for drainage from the vault of the vagina. This silicone vaginal pessary designed and produced in various sizes, meets the above criteria.

Instruct the patient to report any discomfort. The patient should return in twenty four hours for first examination. The vaginal obturator should be removed every day or two for cleaning and can be washed with mild soap and water and then rinsed before reinsertion. Have the patient return in about three days for second examination and then schedule monthly return visits.

184

DISTRIBUTED BY:
BIO•AM™
Bioteque America, Inc.
340 East Maple Avenue
Langhorne, Pa 19047
Tel. (215) 750-8071
Fax (215) 750-8073

Adverse Reactions:
During each visit the vagina should be checked for evidence of unnecessary pressure or allergic reaction.

Precautions:
Patient should be questioned concerning douching, discharge, disturbance of bowel function and urination.

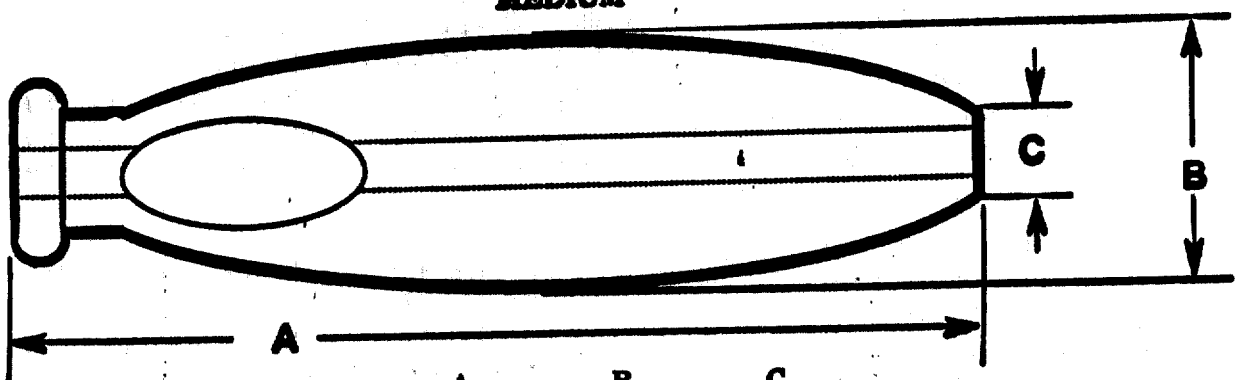
Instructions for the Patient:
Your doctor has recognized the need for wearing a device or obturator within the vagina that will keep the vaginal cavity from contracting during its healing phase or to relax the spasms of the muscles around the vaginal entrance. When the obturator is in its place you may be conscious of a mild feeling of pressure, but there should be no pain. (Should the device become painful, bring the matter promptly to your physician's attention). There is a small knob at the outside end of the obturator that can be grasped to facilitate its insertion and removal.

When inserting the obturator your pelvic muscles must be relaxed. With one hand separate the labia minora and with the other insert the blunt end of the well lubricated (use any water soluble gel) obturator into the vaginal cavity and gently make pressure, pushing the obturator into the vagina until it stops and the knob end is comfortably within the vagina. The obturator should be turned so that one flattened surface near the tip will come to rest beneath the ureathra, (which is the external opening into the bladder), and replaced more easily if you wear a supportive sanitary napkin when the obturator is in place.

The obturator should be removed from time to time, as your physician will instruct, washed with soap and water and replaced.

Instructions courtesy of David H. Nichols, M.D.
Sizes Available: Small, Medium, Large.

MEDIUM



	A	B	C
SMALL	116.75 mm	30.75 mm	13.75 mm
MEDIUM	125.50 mm	33.50 mm	14.75 mm
LARGE	133.75 mm	41.70 mm	15.75 mm

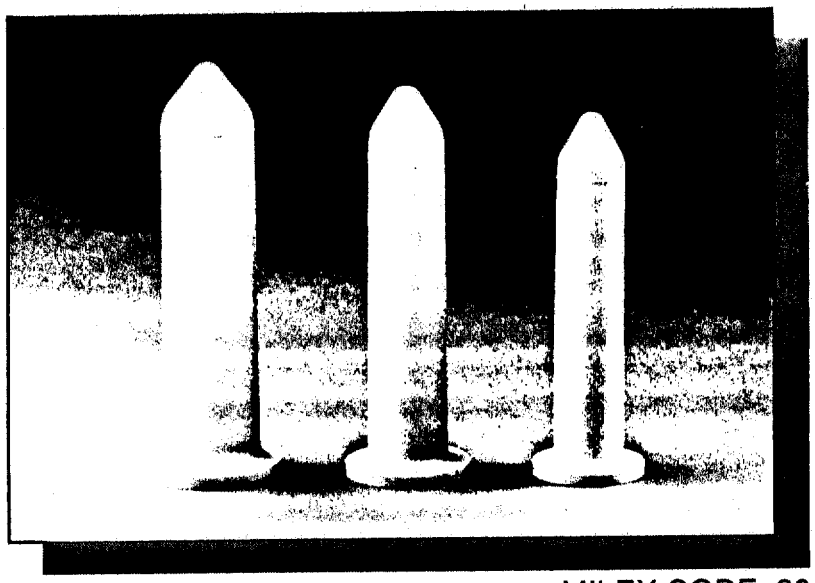
PATENT PENDING

(b) (4) Drawing

(b) (4) Drawing

MILEX

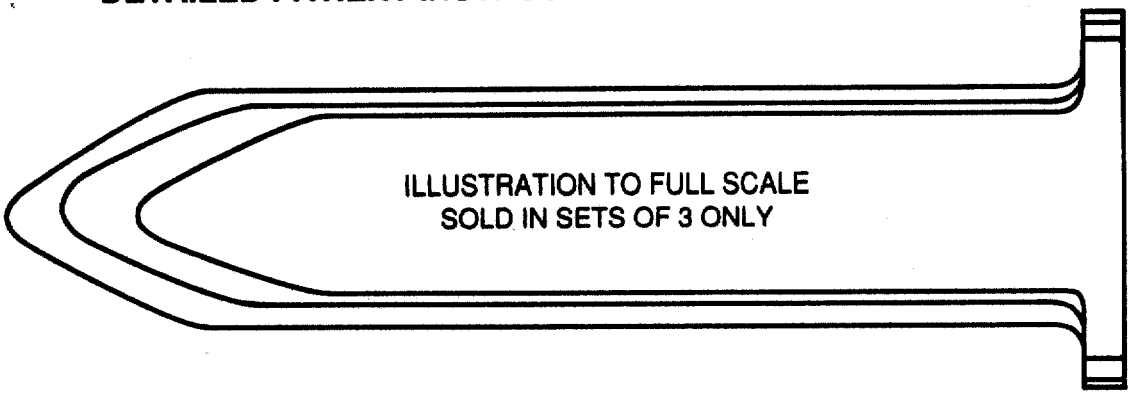
silicone



MILEX CODE: 20

AVAILABLE ONLY IN SETS OF 3 GRADUATED SIZES.

DETAILED PATIENT INSTRUCTIONS INCLUDED WITH EACH SET.



HYMENAL SILICONE DILATORS (VAGINAL)

Small	4-7/8" x 7/8" x 15/16"	or	124mm x 22mm x 24mm
Medium	5-1/4" x 1" x 1-1/16"	or	133mm x 26mm x 27mm
Large	5-9/16 x 1-3/16" x 1-5/16"	or	141mm x 30mm x 34mm

Sterilization Instructions:

1. Autoclave at 15 pounds pressure (250ºF) for 15 minutes.
2. Boil for 15 minutes.
3. Cold sterilize.

1988

Dow Corning
DOW CORNING Medical

SILASTIC® Q7-4840 A/B Medical Grade Liquid Silicone Rubber (LSR)

DESCRIPTION

SILASTIC® Q7-4840 A/B Medical Grade Liquid Silicone Rubber (LSR) is a two-part silicone elastomer specifically designed for liquid injection molding. Because of its consistency, it can also be utilized for crosshead and support extrusion applications. When the A and B components are mixed together in equal portions, the liquid will cure to a tough, rubbery elastomer via addition cure (platinum cure) chemistry.

Advantages of this product include:

- Solventless
- Translucent
- Pigmentable
- Two components mixed at a 1:1 ratio
- Long pot life at room temperature
- Rapid cure rate at elevated temperatures
- Medium-low durometer
- No volatile by-products
- Post-cure not required but can be used as an option to stabilize properties
- Complies with FDA regulations 21 CFR 177.2600, covering rubber articles intended for repeated food contact
- Liquid system permits high quality parts to be molded at rapid rates

APPLICATIONS

SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber is especially designed for manufacturing health care devices by either liquid injection molding or liquid extrusion. It can be utilized for bonding various silicone elastomer substrates. Some specific applications include:

- Precision molded parts
- Molded rubber stoppers and closures
- Encapsulated electronic parts
- O-rings
- Cloth coating
- Wire coating

The purchaser should thoroughly test products made in part or otherwise incorporating SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber to determine the acceptability of the product's performance in a specific application.

INSTRUCTIONS FOR USE

Blending

SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber is supplied as A and B components that must be combined in equal portions prior to use. Airless mixing, metering, and dispensing equipment is recommended for production operations. Information is available from Dow Corning on the suppliers of suitable pumping, mixing, and molding equipment. If hand mixing, a vacuum of 28 to 29 inches of mercury will sufficiently de-air the material in 20 to 30 minutes. At this reduced pressure, the material will normally rise above its original volume before collapsing.

Pot Life

After the A and B components are mixed, SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber will remain usable for 24 hours at room temperature. Refrigeration at lower temperatures -23°C (-10°F) significantly extends the usable life after mixing.

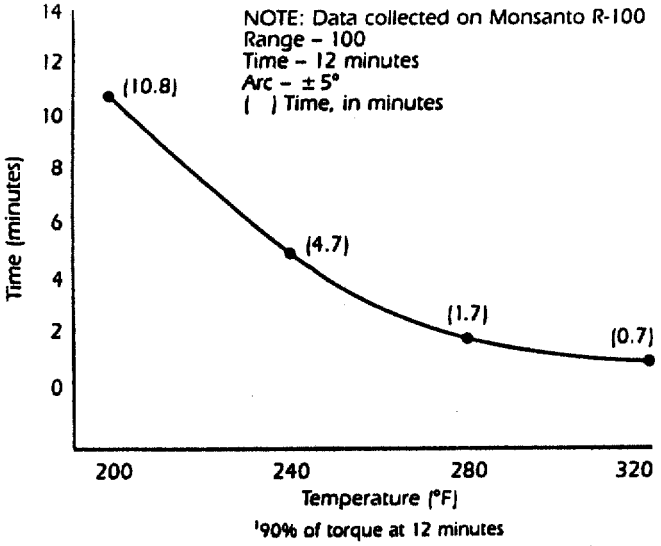
Vulcanization

Cure is initiated by the application of heat. Raising the temperature of the mass to 110°C (230°F) results in a very rapid cure to a tough elastomeric material. The premeasured catalyst gives the stock a fixed cure rate that can be measured on a Monsanto rheometer.

189

Mixing the two components in anything other than a 1:1 ratio will change the cure rate of the elastomer and the physical properties of the resulting part. This off-ratioing should be thoroughly evaluated by the user if it is to be considered as an option. The rate of cure may be varied by adjusting temperature as demonstrated in Figure I.

FIGURE I: Cure Rate[1] of SILASTIC® Q7-4840 A/B Medical Grade Liquid Silicone Rubber



[1]90% of torque at 12 minutes

Caution: The cure may be inhibited by traces of amines, sulfur, nitrogen oxide, organotin compounds, and carbon monoxide. Because organic rubbers often contain these substances, they should not come in contact with the uncured elastomer. For example, it has been demonstrated that extracts from certain latex gloves can inhibit the platinum cure chemistry. Catalyst residues from silicone Room Temperature Vulcanization (RTV) elastomers and peroxide-cured silicone elastomers may also inhibit the cure.

BIOCOMPATIBILITY

Biocompatibility tests, which meet or exceed current USP Class VI Plastics Tests, have been performed on vulcanized SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber and are shown in Table I. In addition, every production lot of elastomer is tested for levels of trace metals and for absence of cytopathic effects using tissue cell culture test (direct contact method).

TABLE I: Biocompatibility of SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber

Test	*Results*
Hemolysis, percent	<1
Pyrogenicity	Nonpyrogenic*
Intracutaneous Injection	Nonirritating*
Systemic Injection	Nontoxic*
Skin Sensitization	Nonsensitizing*
Intramuscular Implant	
10 days	Nonreactive*
30 days	Nonreactive*
90 days	Nonreactive*
Tissue Cell Culture	No Cytopathic Effect

*Based on comparison with defined USP negative controls.

SHIPPING LIMITATIONS

None.

STORAGE AND SHELF LIFE

The shelf life of unblended SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber A and B components is 6 months from date of shipment.

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications.

Property[1]	Result Q7-4840	Method ASTM	Method CTM[2]
As Supplied			
Color	Translucent		0176
Extrusion Rate[3], grams/minute	190		0364
As Cured			
Specific Gravity	1.13	D 792	0022
Durometer Hardness, Shore A, pts	43	D 2240	0099
Tensile Strength, psi	1300	D 412	0137A
Elongation, percent	500	D 412	0137A
Tear Strength, Die B, ppi	150	D 624	0159A
Tissue Culture	No CPE	–	0274
Metals, ppm		–	0571
Al	200 max.		
Na, Mg, Ca	100 max.		
P, Ti, Fe	50 max.		
Sb, Ge, Mn, Mo, Pb, Sn, Cr, Bi, V, Ag, Co, Ni, Cu, Zr, Ba, As, Zn, Se, Cd, Hg, Tl	10 max. each		

[1]All physical properties measured from 0.075-inch thick ASTM slab molded 5 minutes at 150 C (302 F) and equilibrated 24 hours at room temperature.

[2]Corporate Test Method (CTM) procedures correspond to standard ASTM tests and are available upon request.

[3]Test Parameters: 90 psi and 1/8-inch orifice.

Specification Writers: Please contact Dow Corning Corporation, Specification Dept., Midland, Michigan 48686-0994, before writing specifications on this product.

PACKAGING

SILASTIC® Q7-4840 Medical Grade Liquid Silicone Rubber is available in 80-lb (36.3-kg) and 900-lb (409-kg) kits, each with equal size containers of A and B components.

ORDERING

To order this product, call 1-800-248-2481, or contact our Sales Offices in Irvine, California; Buffalo Grove, Illinois; or Mount Olive, New Jersey. For global location information, please call.

PATENT POSITION

A composition prepared by mixing part A and part B of SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber is claimed in Dow Corning's U.S. Patent No. 4,162,243. Dow Corning intends to enforce this patent, but will offer licenses thereunder. If a license is needed, Dow Corning will ship the product in containers which bear a label license, and the invoice will include a statement of the royalty due. Alternatively, upon written request, Dow Corning will offer a license agreement at a comparable royalty rate under which the licensee may handle its own accounting of royalties due, regardless of the source of material.

SILASTIC® – This registered trademark is the brand name for Dow Corning's silicone elastomer products, materials and related products. Only Dow Corning may identify its products with the trademark SILASTIC®. The work is not a synonym for silicone elastomer and it is improper to use it without capitalization or to use it to identify another manufacturer's materials. Since it may not be used by others, the appearance of the word SILASTIC® on a medical product assures that it is of the highest quality and comes only from Dow Corning.

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

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(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

DRAERD 510(k) Summary/Statement Certification

This document or its equivalent must be completed and included with each 510(k) submission.

I, Denis Dorsey (type/print name) as President (Title)

of Biotesque NA. Inc (Company Name) certify that (check either 1 or 2):

☐ 1. This premarket notification contains a summary of safety and effectiveness information upon which an equivalence determination could be based. This summary does not contain any confidential information and is fully releasable. **(NOTE:** The summary must be provided as a separate section of the submission.)

☑ 2. Biotesque NA. Inc (Company Name) will make available to interested persons upon request, the safety and effectiveness information in this premarket notification that is relevant to an assessment of substantial equivalence.

Denis Dorsey
Signature

3/29/94
Date

204

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

MAR - 9 1994

Mr. Denis P. Dorsey
President
Bioteque America, Inc.
340 E. Maple Avenue, Suite 102
Langhorne, Pennsylvania 19047

Re: K920633/B
Nichols Vaginal Stent
Dated: July 15, 1993
Received: August 24, 1993

Dear Mr. Dorsey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We still cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following information:

Device Description

1. As requested before, please provide a complete description of your device, including diagrams and photographs. (The engineering diagram you included does not adequately illustrate the two different designs.) This information should be provided for both models of your device. Compare your stent to a legally marketed stent, in a comparison table, in terms of indications for use and technological characteristics. The comparison should address the following:

   a. indications for use;
   b. design configuration(s);
   c. dimensions;
   d. component material(s); and
   e. physical properties (e.g., flexure, smoothness, etc.).

   Specifically identify the name of the predicate device and its manufacturer. It is imperative to include diagrams and/or photos of the predicate device, as well as labeling, for comparison.

   Clearly identify the raw materials from which your device is made, and provide the chemical and physical specifications for these materials.

2. As requested before, please provide a complete listing of all component materials, with their respective chemical and physical specifications. It remains unclear what your stent will be made from, since you identify a different material with each 510(k) amendment.

3. As requested before, please provide a description of the manufacturing process for your device. Your last response indicates that, *if required*, you will use Loctite Nuva-Sil™ 84 or 88 as the bonding material (adhesive). Please provide additional information on this material, as specified in #2 above.

Toxicity Data

4. As requested before, provide data from the toxicological testing of your device, in its final manufactured form. Please refer to the *Tripartite Biocompatibility Guidance for Medical Devices*, provided to you in our previous correspondence. This type of testing should include data on mucosal irritation, sensitization, as well as acute and chronic toxicity.

Device Labeling

5. As requested before, please provide complete professional and patient labeling to include the indication(s) for use, contraindications, precautions, warnings, adverse reactions, and instructions for use. Your proposed revised labeling did not fully address our concerns. In particular, the following specific revisions should be incorporated into your labeling:

   a. Physician labeling for indications for use should include guidance regarding the choice of hollow versus solid stents.

   b. Both physician and patient labeling should include the recommended device wear-times, cleaning instructions, and recommended lubricants.

   c. Both physician and patient labeling should include a diagram of the device with pictorials to illustrate insertion and removal of the device.

   d. Patient labeling should include a section entitled *Adverse Effects*, that lists all potential risks and describes how to minimize and/or identify them. Also, include instructions which help the user identify any device defects that result from aging or other causes.

   e. Both physician and patient labeling must state prominently in your labeling that your device is intended for single patient use.

The Safe Medical Devices Act of 1990 (SMDA) requires all persons submitting a premarket notification to include either (1) a summary of safety and effectiveness information in the submission upon which an equivalence determination could be based, OR 2) a statement that such information will be made available to interested persons upon request. We cannot issue a final decision on your 510(k) unless you comply with this requirement. Please complete the enclosed form and return, with attachments if any.

The additional information should be submitted in duplicate, referencing the 510(k) number above to:

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

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations.

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days, it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Mr. Colin M. Pollard, at (301) 594-1180. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number 1-800-628-2041 or at (301) 443-6597.

Sincerely yours,

Robert R Matthys /

for Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DRAERD 510(k) Summary/Statement Certification

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_____ _____

Signature Date

510(K) ROUTE SLIP

510(k) NUMBER K920633 PANEL OB DIVISION DRAER BRANCH OGDB

TRADE NAME NICHOLS VAGINAL STENT

COMMON NAME

PRODUCT CODE ___

APPLICANT BIOTEQUE AMERICA, INC.
SHORT NAME BIOTAMER
CONTACT DENIS DORSEY
DIVISION
ADDRESS 51 RAINLILY ROAD
LEVITTOEN, PA 19056
PHONE NO. (___) ___-____ FAX NO. (___) ___-____

MANUFACTURER BIOTEQUE AMERICA, INC. REGISTRATION NO. 2529577

DATE ON SUBMISSION 27-JAN-92 DATE DUE TO 510(K) STAFF 07-NOV-93

DATE RECEIVED IN ODE 12-FEB-92 DATE DECISION DUE 22-NOV-93

DECISION __ DECISION DATE

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	29-MAY-92	29-MAY-92	27-AUG-92	14-AUG-92	
S002	15-JUL-93	24-AUG-93	07-NOV-93	22-NOV-93	09-MAR-94

CORRESPONDENCE	SENT	DUE BACK	
C003	09-MAR-94	08-APR-94	HOLD LETTER
C001	29-APR-92	29-MAY-92	HOLD LETTER
C002	14-AUG-92	13-SEP-92	HOLD LETTER

910

Mr. Denis P. Dorsey
President
Bioteque America, Inc.
340 E. Maple Avenue, Suite 102
Langhorne, Pennsylvania 19047

Re: K920633/B
Nichols Vaginal Stent
Dated: July 15, 1993
Received: August 24, 1993

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Center for Devices and Radiological Health
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Rockville, Maryland 20850

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Sincerely yours,

/S/ BG Fg

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

213

cc: HFZ-401
HFZ-470
DO
CMPollard
Disk\Sue\510K\K920633B.AI
Draft: 3/04/94:slj
Final:BAStuart:3-8-94

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-470	Pollard	3/8/94						
HFZ-470	Gosling	3/9/94						

☆ U.S. GOVERNMENT PRINTING OFFICE 1991-519-771

Memorandum

Date

From REVIEWER(S) - NAME(S) COLIN POLLARD (HFZ-470)

Subject 510(k) NOTIFICATION K920633/S2

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.

X (C) Requires more data. requested in previous letter.

_____ (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

} enclosure

☐ 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:

_____

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

_____

REVIEW: Colin M Pollard (BRANCH CHIEF) | OGDB (BRANCH CODE) | 3/8/94 (DATE)

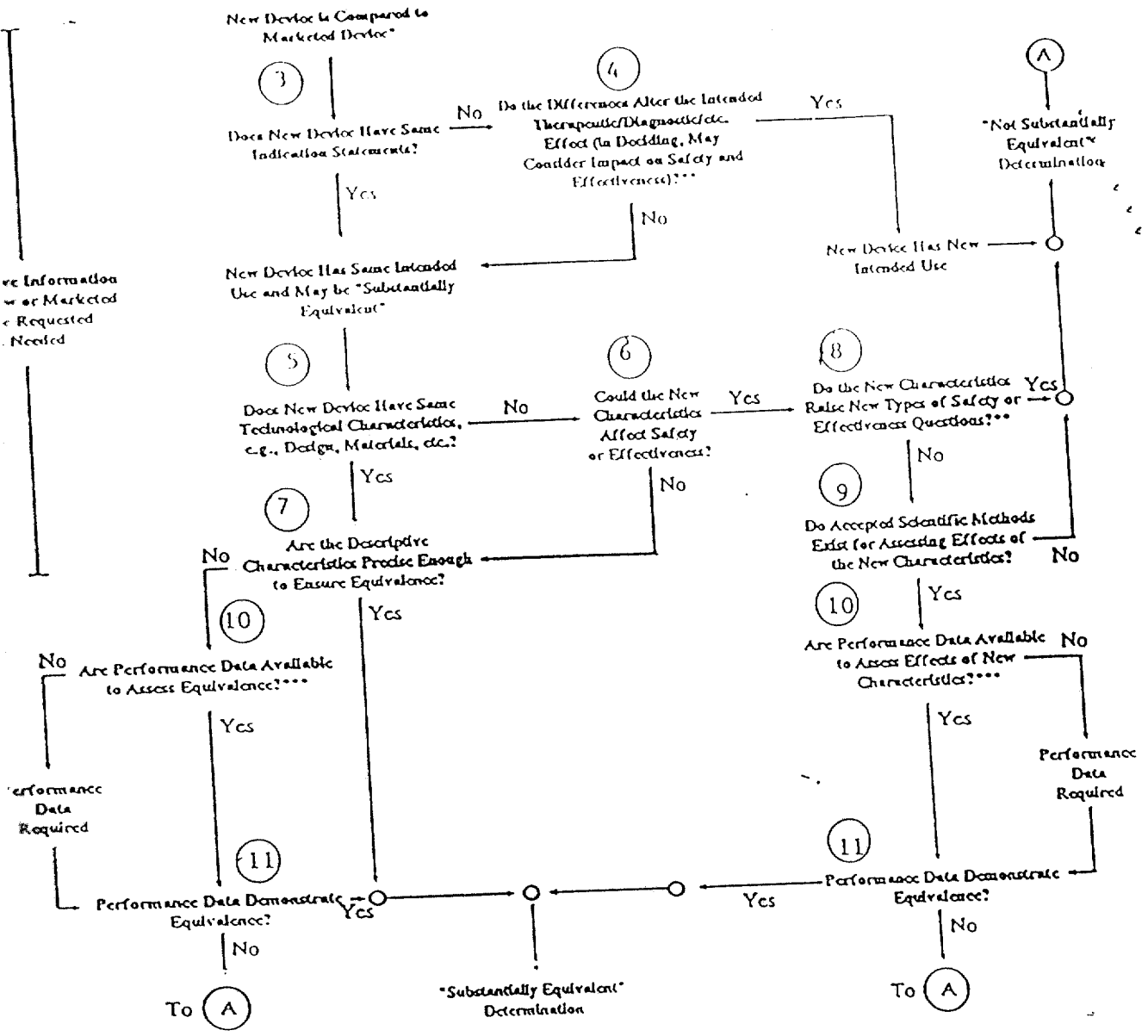
FINAL REVIEW: R Rathun for [illegible] (DIVISION DIRECTOR) 3/9/94 (DATE)

DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

215

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.

OBGD

K920633

Reviewer: Colin Pollard
Biomedical Engineer

Division/Branch: DRAERD/ADOU/OGDB
(HFZ-470)

Proprietary Trade Name: Counseller/Nichols Vaginal Stent
Common Name: Vaginal Stent

Product to which compared: • Conseller Type Vaginal Stent (V. Mueller Co.)

Applicant: Bioteque America, Inc.
340 E. Maple Ave., Suite 102
Langhorne, PA 19047

Contact: Mr. Denis Dorsey
Phone: 215-750-8071

DEVICE DESCRIPTION

1. *Intended Use:*

Provide a brief description of the clinical purpose of this device, including indication(s) for use and any relevant promotional claims.

This device is an obturator that is intended to be used after vaginoplasty surgery to distend the vaginal canal during the post-operative healing process to prevent unwanted contraction of the scar. Produced in various sizes, the vaginal stent is fitted and inserted by the physician and remains in place for up to several weeks.

The stent is removed, cleaned, and re-inserted by the patient from time to time, per physician instructions.

The device is not provided sterile or required to be sterile, but is intended for use only by a single patient, and cleaning periodically is important.

2. *Physical Description:*

	YES	NO
• 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 single use?	___	✓
• Is the device home use?	✓	___
• Is the device for prescription?	✓	___
• Does the device contain a drug or biological product as a component?	___	✓
• Is this device a kit?	___	✓

Provide a brief overview of the device, its design, principle of operation, and functional/performance characteristics.

The Bioteque Counseller/Nichols vaginal stent is an elongated ovoid-shaped vaginal obturator. The stent is not solid, but comes in two configurations: one with central 10 mm tubal openings on either side, the other open only at one end. The 510(k) describes three (3) sizes, but has not definitively specified the stent material, changing from polyethylene, Zytel® nylon resin, and silicone.

Dimensional specifications are given as follows:

	Size 1 (small)	Size 2 (medium)	Size 3 (large)
Length	4.43"	5.27"	6.1"
Outer Diameter	1.47"	1.64"	1.88"
Inner Tubular	approx. half-inch ---------->		

Physical characteristics of the stent are not provided.

REVIEW ANALYSIS

Provide an overview of the review principles and findings that were used to support the reviewer recommendation.

(b) (4)

[redacted]

(b) (4)

[redacted]

Substantial Equivalence (SE) Decision Making Documentation

		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 YES, STOP -> SE

Bioteque needs to fully and adequately address the review concerns raised in our previous AI letter.

REVIEWER RECOMMENDATION

Request additional information -- previously requested

Colin M Pollard March 3, 1994
Colin Pollard Date

CMP 3/8/94
Chief, Ob/Gyn Devices Branch Date

/ / Concur

/ / Do Not Concur

Comments:

220

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

August 27, 1993

BIOTEQUE AMERICA, INC.
51 RAINLILY ROAD
LEVITTOEN, PA 19056
ATTN: DENIS DORSEY

510(k) Number: K920633
Product: NICHOLS VAGINAL STENT

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above 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.

The Safe Medical Devices Act of 1990, 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. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at 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

K 920633/S2

July 15, 1993

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HZF-401)
1390 Piccard Drive
Rockville, Maryland 20850

RE: 510 (k) Number: K920633/A

Re-submission to FDA inquiry dated 8/14/1992

Attention: Document Mail Clerk

NOTICE #1: Change of Address

FROM

BIOTEQUE AMERICA, INC.
51 RAINLILY ROAD
LEVITTOWN, PA 19056

TO

BIOTEQUE AMERICA, INC.
340 E. MAPLE AVENUE - SUITE 102
LANGHORNE, PA 19047

NOTICE #2: Change of K920633/A Name

FROM

NICHOLS VAGINAL STENT

TO

PESSARY FLEXIBLE SILICONE NICHOLS

1. Device Description and Comparison to a Legally Marketed Device

This is to notify you of the intentions of Bioteque America, Inc. to market the following device:

Classification Name: PESSARY, Vaginal
Classification Number: 85HHW
Common Name: PESSARY
Proprietary Name: PESSARY FLEXIBLE SILICONE NICHOLS

Establishment Registration Number: From form FDA 2891 - 2529577

Classification: The vaginal PESSARY would most likely be reviewed by the FDA's Obstetrics and Gynecology Device Panel. The classification number is 85HHW, the regulation number is 884.3575, and the device is listed as class II.

Performance Standards: Not applicable

Label, Labeling, Promotional Material, and Drawings: Draft copies are enclosed.

Substantial Equivalence: The Pessary Flexible Silicone Nichols is similar in function to the Gramm-Field Grafco Gellhorn Pessary, the Bioteque America, Inc. Silicone Gellhorn Pessary (K920187), and the Milex Gellhorn Pessary. The design of the Pessary Flexible Silicone Nichols is modified to increase the "stem" diameter and length while reducing the Gellhorn base ring to match the dimensions extended stem.

Material: The material composition is medical grade silicone Q7-4840 A/B by Dow Corning Medical that complies with FDA regulations 21 CFR 177.2600. Bonding material (adhesive) if required, is Loctite Nuva-Sil™ 84 or 88.

Packaging: The Pessary Flexible Silicone Nichols will be packaged individually in a sealed polybag with instructions inclosed. There will be 25 Pessary Flexible Silicone Nichols per box (maximum).

Bioteque America, Inc. considers the intentions to market this substantially equivalent device as company confidential information and therefore requests the FDA to act accordingly. We have not disclosed the intent to market this device to anyone and have taken all necessary precautions to protect this confidentially.

We also would appreciate the FDA's earliest attention to this 510(K) submission. Please do not hesitate to call Bioteque America, Inc. at 215 750-8071 or 8072 at your convenience with regards to any questions concerning this submission.

Sincerely,

Denis Dorsey

President, Bioteque America, Inc.

Enclosures

PROMOTIONAL MATERIAL

PESSARY FLEXIBLE
SILICONE NICHOLS (picture)

(see enclosed engineering drawings) B-012292

For Single Patient Use Only

CAUTION:
Federal law restricts ~~this~~ tested this device to or on the order of a physician.

INDICATIONS:

For the correction of marked prolapse or procidentia.

CONTRAINDICATIONS:

Pessaries are contraindicated in acute genital tract infections or pelvic infections.

DIRECTIONS FOR USE:

Fitting requires a trial of sizes to determine the proper Pessary Flexible Silicone Nichols.

#1. Perform a normal pelvic examination prior to the introduction or fitting of a pessary. The size selection is more or less trial and error, yet the pelvic exam helps to determine the selection of the appropriate size. *NOTE: The flexibility of the Pessary Flexible Silicone Nichols simplifies insertion and removal.*

#2. The Pessary Flexible Silicone Nichols should be inserted base (opposite the removal stem) first onto the introdus. After insertion, the stem should be in the downward position.

#3. The pessary should not dislodge by standing, sitting, squatting, or bearing down.

324

NOTE: The pessary should be large enough to do its designed function however, you do not want it to cause undue pressure or discomfort.

TO REMOVE:

#1. Gently pull the knob on the pessary to bring the pessary closer to the introdus and within fingers reach.

#2. Use fingers to open the labia for easy removal.

#3. Completely wash the pessary with a mild soap and warm water.

#4. Check the vagina for any evidence of pressure of sensitivity to the pessary. Also, question the patient about douching irritations and if there has been any improvement in her personal symptoms.

#5. It is necessary to check the fit of the pessary to be sure of the correct size for continued patient comfort and relief.

#6. Schedule follow-up visits to fit the needs of the individual patient.

SUGGESTED PATIENT FOLLOW-UP:

#1. Report any discomfort immediately.

#2. Return in 24 to 48 hours to make sure the patient is not allergic to the pessary.

#3. Patient should be instructed to remove the pessary every day or two for cleaning.

#4. Follow-up is then gradually lengthened to one to two month intervals.

Instructions courtesy of David H. Nichols, MD

Sizes Available: Small, Medium, and Large

BACKGROUND FOR THE PHYSICIAN:

There are not uncommon instances where among those women with symptomatic and severe genital prolapse a surgical reconstruction is not feasable at a particular time. Provided that there is a palable levator hiatus, a properly fitted intravaginal pessary may provide long term relief of symptoms. Such a pessary should be available in a variety of shapes to fit a particular need, be chemically inert within the vagina, and capable of easy insertion and removal for cleaning and for vaginal rest, even by the patient herself if she desires. It must also be affordable. The Silicone Donut Pessary meets these requirments. The pessary patient, properly fitted, should feel comfortable with the pessary in place, and in fact be unaware of its presence once it has been fitted. Traditionally the pessary has been fashioned from bakelite, hard rubber or lucite, because these are rigid the patient may encounter difficulty and discomfort during insertion and removal. A smooth firmly soft pessary which can be manually folded to ease insertion should, when in place, immediately resume its original supportive shape. Removal of the pessary, by either physician, nurse, or the patient should be easy and comfortable. This pessary meets all of the above requirements and is available in an assortment of sizes. There should be adequate drainage within the pessary to preclude the accumulation of vaginal or uterine secretions in the vault of the vagina behind the pessary.

The size chosen for the patient should be the largest that the vagina can retain comfortably, and when in place the physician should be able to insert an examining finger between the outer edge and the vaginal wall assuring patient comfort and virtually eliminating the risk of pressure necrosis. After the pessary has been fitted the patient should arise, walk briefly around the examining room making sure the pessary can be retained, and given a final quick examination to determine that it is in its proper place. The patient should be re-examined within a week to reconfirm the above and the proper sizing.

The pessary should be removed for soap and water cleaning and inspection of the vagina for irritation every other month thereafter. If the patient wishes to actively participate in her care she can be instructed in removing and replacing it herself, and since prolapes becomes eccenuated by gravity when the patient is on her feet, the pessary can be removed at bedtime upon retiring and reinserted upon arising the following morning.

Because the pessary, even though soft and flexible, is a foreign body in the vagina the patient should be told to expect a certain amount of vaginal discharge. This will be less if the patient is postmenopausal and has been taking estrogen replacement therapy.

Background information courtesy of David H. Nichols, M.D.

2216

INSTRUCTIONS TO THE PATIENT:

To relieve the symptoms of your genital prolapes the physician has inserted a plastic vaginal support known as a pessary. When properly fit it should be comfortable for you, to the extent that whether standing or reclining you should be unaware of its presence.

Bowel and bladder habits should be unaffected by the pessary, or even improved while it is in place.

The pessary should be removed for cleaning and reinsertion from time to time, as you physician will instruct.

The wearing of a pessary will occasionally be associated with the production of a small amount of non-bloody discharge. This is harmless, and if without syptoms, need be no cause for concern. Should you observe any bleeding component to the discharge call it, or any discomfort, to your physician's attention that it may be properly evaluated.

Instructions courtesy of David H. Nichols.

(b) (4) Drawing

(b) (4) Drawing

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Material Safety Data Sheet

(b) (4) Certificate of Compliance USP Biological Test

(b) (4) Certificate of Compliance USP Biological Test

(b) (4) Certificate of Compliance USP Biological Test

Dow Corning
DOW CORNING Medical

SILASTIC® Q7-4840 A/B Medical Grade Liquid Silicone Rubber (LSR)

DESCRIPTION

SILASTIC® Q7-4840 A/B Medical Grade Liquid Silicone Rubber (LSR) is a two-part silicone elastomer specifically designed for liquid injection molding. Because of its consistency, it can also be utilized for crosshead and support extrusion applications. When the A and B components are mixed together in equal portions, the liquid will cure to a tough, rubbery elastomer via addition cure (platinum cure) chemistry.

Advantages of this product include:

- Solventless
- Translucent
- Pigmentable
- Two components mixed at a 1:1 ratio
- Long pot life at room temperature
- Rapid cure rate at elevated temperatures
- Medium-low durometer
- No volatile by-products
- Post-cure not required but can be used as an option to stabilize properties
- Complies with FDA regulations 21 CFR 177.2600, covering rubber articles intended for repeated food contact
- Liquid system permits high quality parts to be molded at rapid rates

APPLICATIONS

SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber is especially designed for manufacturing health care devices by either liquid injection molding or liquid extrusion. It can be utilized for bonding various silicone elastomer substrates. Some specific applications include:

- Precision molded parts
- Molded rubber stoppers and closures
- Encapsulated electronic parts
- O-rings
- Cloth coating
- Wire coating

The purchaser should thoroughly test products made in part or otherwise incorporating SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber to determine the acceptability of the product's performance in a specific application.

INSTRUCTIONS FOR USE

Blending

SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber is supplied as A and B components that must be combined in equal portions prior to use. Airless mixing, metering, and dispensing equipment is recommended for production operations. Information is available from Dow Corning on the suppliers of suitable pumping, mixing, and molding equipment. If hand mixing, a vacuum of 28 to 29 inches of mercury will sufficiently de-air the material in 20 to 30 minutes. At this reduced pressure, the material will normally rise above its original volume before collapsing.

Pot Life

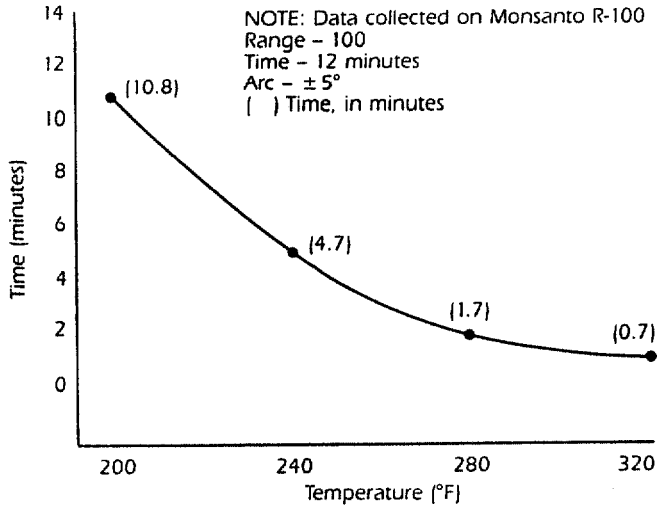
After the A and B components are mixed, SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber will remain usable for 24 hours at room temperature. Refrigeration at lower temperatures -23°C (-10°F) significantly extends the usable life after mixing.

Vulcanization

Cure is initiated by the application of heat. Raising the temperature of the mass to 110°C (230°F) results in a very rapid cure to a tough elastomeric material. The premeasured catalyst gives the stock a fixed cure rate that can be measured on a Monsanto rheometer.

Mixing the two components in anything other than a 1:1 ratio will change the cure rate of the elastomer and the physical properties of the resulting part. This off-ratioing should be thoroughly evaluated by the user if it is to be considered as an option. The rate of cure may be varied by adjusting temperature as demonstrated in Figure I.

FIGURE I: Cure Rate[1] of SILASTIC® Q7-4840 A/B Medical Grade Liquid Silicone Rubber



[1]90% of torque at 12 minutes

Caution: The cure may be inhibited by traces of amines, sulfur, nitrogen oxide, organotin compounds, and carbon monoxide. Because organic rubbers often contain these substances, they should not come in contact with the uncured elastomer. For example, it has been demonstrated that extracts from certain latex gloves can inhibit the platinum cure chemistry. Catalyst residues from silicone Room Temperature Vulcanization (RTV) elastomers and peroxide-cured silicone elastomers may also inhibit the cure.

BIOCOMPATIBILITY

Biocompatibility tests, which meet or exceed current USP Class VI Plastics Tests, have been performed on vulcanized SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber and are shown in Table I. In addition, every production lot of elastomer is tested for levels of trace metals and for absence of cytopathic effects using tissue cell culture test (direct contact method).

TABLE I: Biocompatibility of SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber

Test	*Results*
Hemolysis, percent	<1
Pyrogenicity	Nonpyrogenic*
Intracutaneous Injection	Nonirritating*
Systemic Injection	Nontoxic*
Skin Sensitization	Nonsensitizing*
Intramuscular Implant	
10 days	Nonreactive*
30 days	Nonreactive*
90 days	Nonreactive*
Tissue Cell Culture	No Cytopathic Effect

*Based on comparison with defined USP negative controls.

SHIPPING LIMITATIONS

None.

STORAGE AND SHELF LIFE

The shelf life of unblended SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber A and B components is 6 months from date of shipment.

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications.

Property[1]	Result Q7-4840	Method ASTM	Method CTM[2]
As Supplied			
Color	Translucent		0176
Extrusion Rate[3], grams/minute	190		0364
As Cured			
Specific Gravity	1.13	D 792	0022
Durometer Hardness, Shore A, pts	43	D 2240	0099
Tensile Strength, psi	1300	D 412	0137A
Elongation, percent	500	D 412	0137A
Tear Strength, Die B, ppi	150	D 624	0159A
Tissue Culture	No CPE	–	0274
Metals, ppm		–	0571
Al	200 max.		
Na, Mg, Ca	100 max.		
P, Ti, Fe	50 max.		
Sb, Ge, Mn, Mo, Pb, Sn, Cr, Bi, V, Ag, Co, Ni, Cu, Zr, Ba, As, Zn, Se, Cd, Hg, Tl	10 max. each		

[1]All physical properties measured from 0.075-inch thick ASTM slab molded 5 minutes at 150 C (302 F) and equilibrated 24 hours at room temperature.

[2]Corporate Test Method (CTM) procedures correspond to standard ASTM tests and are available upon request.

[3]Test Parameters; 90 psi and 1/8-inch orifice.

Specification Writers: Please contact Dow Corning Corporation, Specification Dept., Midland, Michigan 48686-0994, before writing specifications on this product.

PACKAGING

SILASTIC® Q7-4840 Medical Grade Liquid Silicone Rubber is available in 80-lb (36.3-kg) and 900-lb (409-kg) kits, each with equal size containers of A and B components.

ORDERING

To order this product, call 1-800-248-2481, or contact our Sales Offices in Irvine, California; Buffalo Grove, Illinois; or Mount Olive, New Jersey. For global location information, please call.

PATENT POSITION

A composition prepared by mixing part A and part B of SILASTIC Q7-4840 A/B Medical Grade Liquid Silicone Rubber is claimed in Dow Corning's U.S. Patent No. 4,162,243. Dow Corning intends to enforce this patent, but will offer licenses thereunder. If a license is needed, Dow Corning will ship the product in containers which bear a label license, and the invoice will include a statement of the royalty due. Alternatively, upon written request, Dow Corning will offer a license agreement at a comparable royalty rate under which the licensee may handle its own accounting of royalties due, regardless of the source of material.

SILASTIC® – This registered trademark is the brand name for Dow Corning's silicone elastomer products, materials and related products. Only Dow Corning may identify its products with the trademark SILASTIC®. The work is not a synonym for silicone elastomer and it is improper to use it without capitalization or to use it to identify another manufacturer's materials. Since it may not be used by others, the appearance of the word SILASTIC® on a medical product assures that it is of the highest quality and comes only from Dow Corning.

(b) (4) Material Safety Data Sheet

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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

August 03, 1993

BIOTEQUE AMERICA, INC.
51 RAINLILY ROAD
LEVITTOEN, PA 19056
ATTN: DENIS DORSEY

510(k) Number: K920633
Product: NICHOLS VAGINAL STENT

This is to notify you that 30 days have elapsed since we requested additional information about your Premarket Notification (510(k)) submission. In accordance with our regulations, 21 CFR 807.87(h), we now consider your 510(k) to be withdrawn.

If you wish to resubmit this 510(k) notification, a new 510(k) number will be assigned and your submission will be considered a new submission.

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

Sincerely yours,

Marjorie Shulman

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

510(K) ROUTE SLIP

10(k) NUMBER K920633 PANEL OB DIVISION DRAER BRANCH OGDB

TRADE NAME NICHOLS VAGINAL STENT

COMMON NAME

PRODUCT CODE ___

APPLICANT BIOTEQUE AMERICA, INC.
SHORT NAME BIOTAMER
CONTACT DENIS DORSEY
DIVISION
ADDRESS 51 RAINLILY ROAD
LEVITTOEN, PA 19056
PHONE NO. (___) ___-____ FAX NO. (___) ___-____

MANUFACTURER BIOTEQUE AMERICA, INC. REGISTRATION NO. 2529577

DATE ON SUBMISSION 27-JAN-92 DATE DUE TO 510(K) STAFF

DATE RECEIVED IN ODE 12-FEB-92 DATE DECISION DUE 27-AUG-92

DECISION DE DECISION DATE 03-AUG-93

SUPPLEMENTS	RECEIVED	DUE	OUT	DUE BACK
C001	29-APR-92	29-MAY-92	29-MAY-92	ADD TO FILE
C002	14-AUG-92	13-SEP-92	03-AUG-93	ADD TO FILE
S001	29-MAY-92	27-AUG-92	14-AUG-92	13-SEP-92

213

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-92-0633

2/19/92

7a 2/21/92 RR

12/27/91

FROM:
BIOTEQUE AMERICA, INC.
ATTN: DENIS DORSEY
51 RAINLILY ROAD

LEVITTOWN, PA 19056

SHORT NAME: BIOTAMER

LETTER DATE	LOGIN DATE	DUE DATE
~~01/27/92~~	02/12/92	05/12/92

TYPE OF DOCUMENT: 510 (k)

CONTROL # K920633

PHONE NO: 215-946-1774
ESTABLISHMENT NO: 2529577

TO:
ODE/DMC

CONT. CONF.: N
STATUS : R
REV PANEL : OB
PAN/PROD CODE(S): OB/ / /

DMC 4/29/92 HD

SUBJECT:
NICHOLS VAGINAL STENT

DECISION:
DECISION DATE: / /

RQST INFO DATE:	/ /	INFO DUE DATE:	/ /
DATE:	/ /	DATE:	/ /
DATE:	/ /	DATE:	/ /
DATE:	/ /	DATE:	/ /
DATE:	/ /	DATE:	/ /
DATE:	/ /	DATE:	/ /

254

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

AUG 14 1992

Mr. Denis P. Dorsey
Bioteque America, Inc.
51 Rainlily Road
Levittown, Pennsylvania 19056-2301

Re: K920633/A
Nichols Vaginal Stent
Received: May 29, 1992

Dear Mr. Dorsey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. You have not adequately addressed deficiency numbers 1, 2, 3, 8 and 9 in our April 29, 1992, letter requesting additional information. In order for us to complete the review of your submission, we require the following information:

Device Description and Comparison to a Legally Marketed Device

1. Provide a complete description of your device including its materials, design, dimensions, physical properties (e.g., hardness, flexibility), surface characteristics, etc. Also, provide detailed schematics of your device. Your current schematics do not clearly differentiate the "two options" (i.e., solid versus hollow) of your device. This information should be provided for both options of your device.

   Compare the above technological characteristics of your device (both designs) and the indication(s) for use to a legally marketed device.

2. Clearly identify the raw materials from which your device is made, and provide the chemical and physical specifications for these materials. (Your original 510(k) stated that your device was made from polyethylene while your amendment states that your device is made from nylon.)

Toxicity Data

3. Provide mucosal irritation, sensitization, acute and chronic toxicity data conducted on your final product to support its safe use. Please refer to the enclosed "Tripartite Biocompatibility Guidance for Medical Devices" for further information.

Device Labeling

4. Provide complete professional and patient labeling which includes indications for use for each device option, if applicable, contraindications, warnings, precautions, adverse reactions and instructions for use (see enclosure). The following specific revisions should be incorporated into your labeling:

a. Provide specific indications for use for your device which describe the clinical conditions for which the device is intended (e.g., post-operative use after reconstructive surgery to help prevent vaginal contracture).

b. Include recommended device wear-times, cleaning instructions and compatible lubricants with your instructions for use. Also, include instructions which help the user identify any potentially aging or damage to the device.

c. State prominently in your labeling that your device is intended for single patient use.

5. Delete all exaggerated claims of safety and effectiveness from your professional and patient labeling, for example "will keep the vaginal cavity from excessive scarring" and "will simulate protective vaginal secretions."

The Safe Medical Devices Act of 1990 (SMDA) requires all persons submitting a premarket notification to include either (1) a summary of safety and effectiveness information in the submission upon which an equivalence determination could be based, OR 2) a statement that such information will be made available to interested persons upon request. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

The additional information should be submitted in duplicate, referencing the 510(k) number above to:

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

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations.

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days, it will be considered and processed as a new 510(k); therefore, all

information previously submitted must be resubmitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Ms. Christine L. Brauer, at (301) 427-1180. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number 1-800-628-2041 or at (301) 443-6597.

Sincerely yours,

Robert R Watts

for Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

257

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-92-0633

8/17/92

FROM: BIOTEQUE AMERICA, INC. ATTN: DENIS DORSEY 51 RAINLILY ROAD LEVITTOWN, PA 19056 SHORT NAME: BIOTAMER	LETTER DATE 01/27/92	LOGIN DATE 02/12/92	DUE DATE 08/27/92
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K920633
	PHONE NO: 215-946-1774 ESTABLISHMENT NO: 2529577		
TO: ODE/DMC	CONT. CONF.: N STATUS : H REV PANEL : OB PAN/PROD CODE(S): OB/ / /		

SUBJECT:
NICHOLS VAGINAL STENT

DECISION: DECISION DATE: / /	RQST INFO DATE: 04/29/92 DATE: 08/14/92 DATE: / / DATE: / / DATE: / / DATE: / /	INFO DUE DATE: 05/29/92 DATE: 09/13/92 DATE: / / DATE: / / DATE: / / DATE: / /

SUPPLEMENT: 01 LTR DATE: 920529 LOGIN DATE: 920529

288

AUG 14 1992

Mr. Denis P. Dorsey
Bioteque America, Inc.
51 Rainlily Road
Levittown, Pennsylvania 19056-2301

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Nichols Vaginal Stent
Received: May 29, 1992

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NO

Device Labeling

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29

a. Provide specific indications for use for your device which describe the clinical conditions for which the device is intended (e.g., post-operative use after reconstructive surgery to help prevent vaginal contracture).

b. Include recommended device wear-times, cleaning instructions and compatible lubricants with your instructions for use. Also, include instructions which help the user identify any potentially aging or damage to the device.

c. State prominently in your labeling that your device is intended for single patient use.

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

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Sincerely yours,

ISI BG In

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z-470	Brauer	8/7/92						
Z470	Pollard	8/11/92						
Z470	Yin	8/11/92						

cc: HFZ-401
HFZ-470
DO

CLBrauer
C:\WP51\510K\K920633A.AI
Draft: 08/06/92:slj
Redraft: 8/06/92:slj
Final: 08/07/92:slj

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date 8/5/92

From REVIEWER(S) - NAME(S) C Braun

Subject 510(k) NOTIFICATION K920633 /A

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.

X (C) Requires more data.

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Consult w Gene when AI received

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

Request Potential problem & statement provided!

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

X Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

_____

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

_____

REVIEW: Colin M. Pollard (BRANCH CHIEF) | 06DB (BRANCH CODE) | 8/11/92 (DATE)

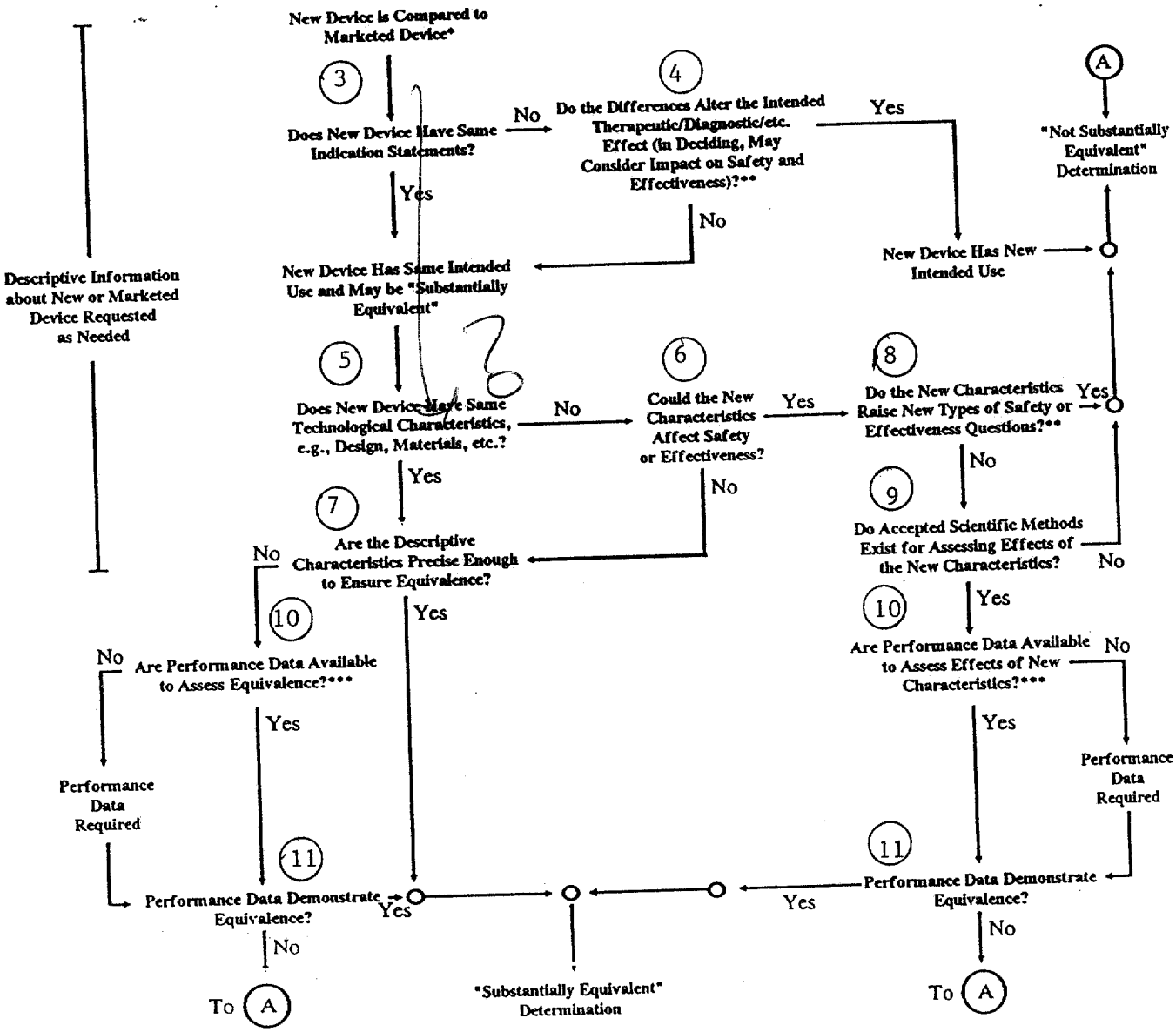
FINAL REVIEW: R Nutty for LKW (DIVISION DIRECTOR) 8/12/92 (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

203

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.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

Document Control Number: K920633/A
Login Date: 05/29/92
90 Day Due Date: 08/27/92
Reviewer: Microbiologist
Division/Branch: DRAERD/OGDB

Applicant and Contact: Bioteque America, Inc.
Attn: Mr. Denis Dorsey
51 Rainlily Road
Levittown, PA 19056-2301

Trade Name: Nichols Vaginal Stent
Common Name: Vaginal Stent

Product To Which Compared: Counseller Plastic Mold

		YES	NO	
1.	IS PRODUCT A DEVICE?	X	___	IF NO STOP
2.	DEVICE SUBJECT TO 510(k)?	X	___	IF NO STOP
3.	SAME INDICATION STATEMENT?	X	___	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 NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	___	___	IF YES GO TO 8
7.	DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	___	___	IF YES STOP -> SE IF NO GO TO 10
8.	NEW TYPES OF SAFETY AND EFFECTIVENESS QUESTIONS	___	___	IF YES STOP-> NSE
9.	ACCEPTED SCIENTIFIC METHODS EXIST	___	___	IF NO STOP-> NSE
10.	PERFORMANCE DATA AVAILABLE	___	___	IF NO REQUEST DATA
11.	DATA DEMONSTRATE EQUIVALENCE	___	___	

365

NARRATIVE DEVICE DESCRIPTION

1. Intended Use:

Vaginal stents are class II medical devices intended for use to support the vagina, hold a skin graft and prevent contracture after reconstructive surgery.

2. Device Description:

	YES	NO
Is the device life-supporting or life sustaining?	___	X
Is the device implanted (short-term or long-term)?	X	___
Does the device design use software?	___	X
Is the device sterile?	X	___
Is the device single use?	___	X
Is the device home use?	X	___
Is the device for prescription?	X	___
Does the device contain a drug or biological product as a component?	___	X
Is this device a kit?	___	X

Device Description and Comparison to a Predicate Device

The Nichols Vaginal Stent is available in three sizes and two designs which allow drainage. The sizes are listed below.

1. Length - 11.25 centimeters (cm)
   Diameter - 3.75 cm
   Circumference - 11.78 cm

2. Length - 13.38 cm
   Diameter - 4.17 cm
   Circumference - 13.1 cm

3. Length - 15.5 cm
   Diameter - 4.77 cm
   Circumference - 15 cm

One design consists of a solid oblong device with a 1 cm hole, and the other design consists of a hollow oblong device with a 4.75 millimeter wall thickness with two 1 cm holes at each end.

The chemical and physical specifications of the materials of the device were requested. The original 510(k) stated that the device was made from polyethylene. However, the amendment states that the device is made from nylon, and specifications for a nylon material have been provided. This discrepancy should be clarified.

A complete description of the device, and comparison to a legally marketed device was requested. This should have included information on the materials, dimensions, physical properties (hardness, flexibility, etc.) and surface characteristics. None of this information was provided. For example, the patient's instructions for use indicate that one area of the device has a flattened surface. This is not clearly indicated on the device diagrams. The information on the predicate device is very important because a vaginal stent has not been cleared through the 510(k) process although the devices were classified (21 CFR 884.3900). * Because the device description is so poor, it is unclear if additional mechanical testing is required. CK Blaner 8/6/92

Biocompatibility Data

Vaginal stents contact vaginal and cervical tissue, and are used for several months following surgery. Vaginal stents, therefore, can be considered long-term implants. Mucosal irritation, sensitization, acute and chronic toxicity data were requested. No data were provided.

Sterility

The device is sterilized with ethylene oxide (EO), and the sterilization cycle will be validated according to the AMMI EO standard. The device will have a sterility assurance level of 10^{-6}, and the maximum EO residues and its derivatives will meet the proposed Federal Register requirements. A brief description of the device packaging was provided.

Device Labeling

Professional and patient labeling were requested, and an enclosure was forwarded to the manufacturer regarding the appropriate format of the labeling. However, labeling was not revised as requested.

3. Recommendation:

The following information should be requested:

Device Description and Comparison

1. Provide a complete description of your device including its materials, design, dimensions, physical properties (e.g., hardness, flexibility), surface characteristics, etc. Also, provide detailed schematics of your device. This information should be provided for both designs of your device.

Compare these technological characteristics of your device (both designs) to a legally marketed device.

2. Provide the chemical and physical specifications for the material from which your device is made. This should clearly identify the raw materials from which your device made. (Your original 510(k) stated that your device was made from polyethylene while your amendment states that your device is made from nylon.)

Toxicity Data

3. Provide mucosal irritation, sensitization, acute and chronic toxicity data conducted on your final product to support its safe use. Please refer to the enclosed "Tripartite Biocompatibility Guidance for Medical Devices" for further information.

Device Labeling

4. Provide complete professional and patient labeling which includes indications for use, contraindications, precautions, warnings, adverse reactions and instructions for use (see enclosure). The following specific revisions should be incorporated into your labeling:

   a. Provide specific indications for use for your device which describe the clinical conditions for which the device is intended (e.g., post-operative use after reconstructive surgery to help prevent vaginal contracture).

   b. Include recommended device wear-times, cleaning instructions and compatible lubricants with your instructions for use. Also, include instructions which help the user identify any potentially aging or damage to the device.

   c. State prominently in your labeling that your device is intended for single patient use.

5. Delete all exaggerated claims of safety and effectiveness from your professional and patient labeling, for example "will keep the vaginal cavity from excessive scarring" and "will simulate protective vaginal secretions."

Christine Brauer

Christine Brauer

Date: 8/5/92

Colin Pollard

Chief, Branch

Date: 8/11/92
Concur / ✓ /
Do Not Concur / /

968

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

MAY 29, 1992

BIOTEQUE AMERICA, INC.
ATTN: DENIS DORSEY
51 RAINLILY ROAD
LEVITTOWN, PA 19056

510(k) Number: K920633
Received: 05-29-92
Product: NICHOLS VAGINAL STENT

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above 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.

The Safe Medical Devices Act of 1990, 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. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

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

209

K920633/A

RE: K920633
Nichols Vaginal Stent
Dated: December 27, 1991
Received: February 12, 1992

Dear Ms. Christine L. Brauer:

With reference to the letter concerning the Nichols Vaginal Stent, we wish to provide the following additional information. We are sorry for any inconvenience and sincerely hope the following information will complete the review of our submission (RE: K920633).

DEVICE DESCRIPTION

Item1. The Nichols Vaginal Stent is similiar in design and function to one marketed prior to May 28, 1976 by the V. Mueller Co., Chicago, Illinois. Please refer to drawing number B-012292 for design demensions and detailed schematics of the device. Also note the surface characteristic of Dupont Zytel® 101 possess ballanced properties- combining strength and stiffness, a high suface temperature and a high level of toughness. It is resistant to repeated impact and have low coefficients of friction because of its hard and smooth surface and excellant resistance to abrasion too. Additional information on Zytel® 101 can be obtained by referencing Duponts Master File.

2. Dupont's Zytel® 101 was selected because of molding viscosity. The industry standard. Zytel® 101 complies with the FDA regulation 21CFR177.1500 "Nylon Resins". Although Dupont does not normally divulge compositional information on their proprietary products, Zytel® 101 is a 66 type nylon resin prepared from the condensation polymerization of hexamethylene diamine and adipic acid. Neither contain any colorants, stabilizers, or additives.

3. Data for the Dupont resin Zytel®101 should be included in the Dupont Master File and/or the 21CFR177.1500 "Nylon Resins".

4, 5, 7. Information concerning the sterilization is included in the reference material.

270

6. The device will be individually wrapped in a Tyvek (peel type) package.

8a.,b.,9. Professional Labeling:

Need to say Single-Patient Use

NICHOLS
VAGINAL
STENT

picture

Bioteque Product # NVS 1

Indications : To distend the vaginal canal during the postoperative phase.

Contraindications : Vaginal stents are contraindicated in the presence of pelvic infections or lacerations.

Instructions for the Physician :

Following the construction of a neovagina or any portion thereof, or following a vaginalplasty operation performed to enlarge a a small vagina, it is usually desired to distend the vaginal canal during the postoperative phase with a device to prevent unwanted contraction of the scar. Such an obturator should be simple, smooth surfaced light in weight, sterilized, capable of removal and insertion by the patient and affordable. It should be available in various sizes comparable to those of the erect penis. Since even a plastic obturator is a foriegn body in the vagina, any vaginal secretions must route through the obturator for drainage from the vault of the vagina. This plastic vaginal stent designed and produced in various sizes, meets the above criteria.

Instruct the patient to report any discomfort. The patient should return in twenty four hours for first examination. The vaginal stent should be removed every day or two for cleaning and can be washed with mild soap and water and then rinsed before reinsertion. Have the patient return in about three days for second examination and then schedule monthly return visits.

Adverse Reactions:

During each visit the vagina should be checked for evidence of unecessary pressure or allergic reaction.

271

Precautions:

Patient should be questioned concerning douching, discharge, disturbance of bowel function and urination.

Instructions for the Patient:

Your doctor has reconized the need for wearing a device or obturator within the vagina that will keep the vaginal cavity from contracting during its healing phase. When the obturator is in its place you may be concious of a mild feeling of pressure, but there should be no pain. (Should the device become painful, bring the matter promptly to your physician's attention). There is a small knob at the outside end of the obturator that can be grasped to facilitate its insertion and removal.

When inserting the obturator your pelvic muscles must be relaxed. With one hand separate the labia minora and with the other insert the blunt end of the well lubricated (use any water soluble gel) obturator into the vaginal cavity and gently make pressure, pushing the obturator into the vagina until it stops and the knob end is comfortably within the vagina. The obturator should be turned so that one flattened surface near the tip will come to rest beneath the ureathra, (which is the external opening into the bladder) , and replaced more easily if you wear a supportive sanitary napkin when the obturator is in place.

The obturator should be removed from time to time, as your physician will instruct, washed with soap and water and replaced.

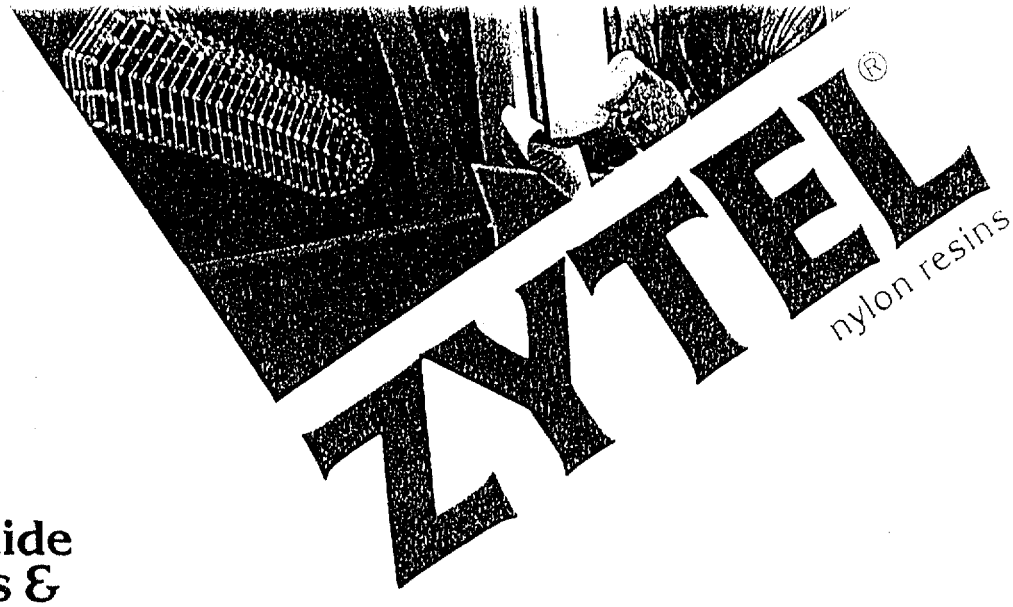
Instructions courtesy of David H. Nichols, M.D.

We sincerely hope these additions and revisions meet with your approval.

Sincerely,

Denis P. Dorsey

Denis P. Dorsey.



General Guide to Products & Properties

ZYTEL is the Du Pont trademark for the many different nylon resins which the company makes. ZYTEL nylon resins are thermoplastic polyamides. Since their invention by Du Pont 40 years ago, they have been the most widely used of all engineering plastics. They are tough, withstand repeated impact and are highly resistant to abrasion and to most chemicals. Molded articles retain their shape at elevated temperatures, are strong in thin sections and have low coefficients of friction. Many compositions are rated V-2 by Underwriters Laboratories Subject 94. Some also qualify for the V-0 rating.

The principal ZYTEL nylon resins may be divided by chemical composition into four basic groups—66 nylon, 612 nylon, 6 nylon and copolymers, all of which may be modified to give special properties. Compositions in any of these groups may also be made with different molecular weights. Properties such as melting point, water absorption and modulus of elasticity are determined primarily by the type of nylon. Impact resistance is affected by the type modifier used (if any) and molecular weight of the nylon. Melt viscosity is determined mainly by molecular weight. Various additives are used to enhance specific properties (e.g., heat resistance, weather resistance, color stability) and to improve processing (e.g., mold release, screw retraction).

ZYTEL nylon resins may be reinforced with glass fibers to increase their tensile strength, stiffness and dimensional stability.

In addition to the commercially coded compositions, there are many "FE" coded resins designed to have specific attributes. These resins are on commercial trial and, if found suitable, may be added to the product line. Information concerning such compositions, as well as any other needs, can be obtained from your Du Pont representative.

Description

Solid granular material. Most of the products are supplied in cylinder cut of 0.090" x 0.100" (2.29 x 2.54 mm) nominal dimensions. Other ZYTEL nylon resins are supplied in a nominally rectangular cut approximately ⅛" x ⅛" x 1/16" (3.18 x 3.18 x 1.58 mm). Some compositions are available in colors.

Packaging

Most ZYTEL nylon resins are packaged in 50-lb (22.6 kg) "pinch-style" bags with a polyethylene-coated foil innerply, 51 lb (23.1 kg) gross, 50 lb (22.6 kg) net weight. Certain ZYTEL nylons are also available in other packages. For example, bulk corrugated cartons with polyolefin liner, one 1180 lb (532.2 kg) gross, 1100 lb (498.9 kg) net weight, and another 1280 lb (580.5 kg) gross, 1200 lb (544.2 kg) net weight.

Disposable four-way entry pallets are used on 2000-lb (907-kg) units of bags and on each bulk corrugated carton.

Zytel® for Moldings and Extrusions

nylon resins

DESIGNATION	DESCRIPTION	CHARACTERISTICS AND MAJOR USES
66 Nylons—Melt at 491°F (255°C)—Stiff and strong over a wide range of temperatures. Excellent toughness and chemical resistance.		
ZYTEL 101	General Purpose—Unlubricated	Basic 66 nylon. Unmodified 66 nylon of molding viscosity. The industry standard.
ZYTEL 101 L	General Purpose—Lubricated	A 66 nylon lubricated for improved machine feed and mold release characteristics. Widely used in injection molding for mechanical parts, consumer products, etc.
ZYTEL 101 F	General Purpose—Fast Cycle	A non-nucleated 66 nylon for optimum molding performance.
ZYTEL 103 HS-L	Heat Stabilized—Lubricated	New, improved heat stabilized 66 nylon designed to retard embrittlement at high service temperatures. Has a 130°C UL rating for electrical use. Optimum stabilization for heat life and good electrical properties. Lubricated for improved machine feed and mold release.
ZYTEL 105 BK-10A	Weather Resistant	Contains well-dispersed carbon black for maximum resistance to weathering.
ZYTEL 122 L	Hydrolysis Resistant	Stabilized to resist hydrolysis and oxidation in long-term exposure to hot water Lubricated for improved machine feed and mold release.
ZYTEL 42	High Viscosity for Extrusion	For extrusion into rod, tubing and complex shapes. Can be molded into parts requiring high impact resistance.
Modified 66 nylons—Melt at 491°F (255°C)—Like 66 nylon with added impact resistance and flexibility.		
ZYTEL 408	General Purpose	Modified resin with superior toughness and moldability.
ZYTEL 408 HS	Heat Stabilized	A new, improved heat stabilized modified 66 nylon.
ZYTEL 408 L	General Purpose—Lubricated	A lubricated version of ZYTEL 408, for improved mold release.
ZYTEL 3189	General Purpose	Impact strength between ZYTEL 408 and ZYTEL ST 801.
Super Tough Nylons—Melt at 491°F (255°C)—Highest impact resistance of any engineering thermoplastic.		
ZYTEL ST 801	General Purpose	Outstanding impact resistance. Good moldability.
ZYTEL ST 801 BK-10	Weather Resistant	Contains well dispersed carbon black for maximum resistance to weathering. outstanding impact resistance.
ZYTEL ST 801 HS	Heat Stabilized	Heat stabilized version of ZYTEL ST 801.
612 nylons—Melt at 414°F (212°C)—Low moisture absorption and excellent dimensional stability.		
ZYTEL 151 L	General Purpose—Lubricated	A 612 nylon lubricated for improved machine feed and mold release.
ZYTEL 158 L	General Purpose—Lubricated	Higher melt viscosity and greater toughness than ZYTEL 151 L. Lubricated for improved machine feed and mold release.
ZYTEL 153 HS-L	Heat Stabilized—Lubricated	Heat stabilized ZYTEL 158 L to retard embrittlement at high service temperatures. Primarily for wire jacketing.
ZYTEL 157 HS-L BK-10	Weather and Heat Resistant—Lubricated	Contains well-dispersed carbon black for maximum resistance to weathering. Heat stabilized. Lubricated for improved machine feed and mold release.
Glass-reinforced Nylons*—Very high strength, stiffness and toughness. Excellent creep resistance and dimensional stability.		
ZYTEL 70G L	General Purpose—Lubricated	66 nylon reinforced with short glass fibers. Available in 13, 33 and 43% nominal glass content by weight.
ZYTEL 70G HS1-L	Heat Stabilized—Lubricated	Heat stabilized ZYTEL 70 G L. Available in 13 and 33% nominal glass content by weight
ZYTEL 70G HR-L	Hydrolysis Resistant—Lubricated	ZYTEL 70 G L with added resistance to hydrolysis and oxidation. Available in 33% nominal glass content by weight.
ZYTEL 71G L	General Purpose—Lubricated	Modified 66 nylon with short glass fibers. Provides additional toughness and outstanding dimensional stability. Available in 13 and 33% nominal glass content by weight.
ZYTEL 77G L	General Purpose—Lubricated	612 nylon reinforced with short glass fibers. Excellent toughness and outstanding dimensional stability. Available in 33 and 43% nominal glass content by weight.
Miscellaneous Products—Including copolymers, modified polymers, blends and unextracted 6 nylon. Properties tailored for specific uses.		
ZYTEL 91 HS1-L	Heat Stabilized	A plasticized resin for flexible tubing and cable jacketing. Has low permeability to "Freon" for use in air conditioner hose.
ZYTEL 109 L	General Purpose—Color Stabilized, Nucleated, Lubricated	Easy processing at the expense of stiffness and high temperature properties. Excellent for heavy section moldings. Color stabilized and nucleated. Lubricated for machine feed and mold release.
ZYTEL 211	General Purpose—Unextracted 6 Nylon	Relatively flexible for high impact uses. Melts at 410°F (210°C). For moldings and extrusion requiring flexibility and toughness
Flame Retarded Nylons		
	General Purpose—Flame Retarded**	Several compositions are available, rated 94V-0 and 94V-1 by Underwriters' Laboratories, Inc.

*All glass-reinforced compositions are lubricated for improved feed and mold release. The properties of glass-reinforced ZYTEL nylon resins are discussed in detail in separate product sheets and in the Product Manual on these resins.

**Note: Does not indicate combustion characteristics under actual fire conditions.

Properties of Zytel®
nylon resins

	Property[3]	ASTM Method	Units	66 NYLONS[1]												612 NYLONS[2]	
				ZYTEL 101 ZYTEL 101 L General Purpose		ZYTEL 42 High Molecular Weight		ZYTEL 105 BK-10A Weather Resistant		ZYTEL 133 L (Nucleated Color Stabilized and Lubricated)		IMPACT MODIFIED ZYTEL 408 ZYTEL 408 L ZYTEL 408 HS		IMPACT MODIFIED ZYTEL ST 801 Super Tough Nylon		ZYTEL 158 L	
				DAM	50% RH	DAM	50% RH	DAM	50% RH	DAM	50% RH	DAM	50% RH	DAM	50% RH	DAM	50% RH
STRENGTH	Tensile Strength																
	−40°F	D 638	psi	16,500	16,000	17,000	16,100	18,700	17,000	–	–	15,100	13,100	11,600	10,000	13,600	13,500
	−40°C		MPa	113.8	110.3	117.2	111.0	128.9	117.2	–	–	104.1	90.3	80.0	68.9	93.8	93.1
	73°F		psi	12,000	11,200	12,400	11,200	13,100	9,000	14,200	10,200	9,000	7,500	7,500	6,000	8,800	8,800
	23°C		MPa	82.7	77.2	85.5	77.2	90.3	62.1	97.9	70.3	62.1	51.7	51.7	41.4	60.7	60.7
	170°F		psi	9,000	5,900	8,500	5,900	9,000	7,300	–	–	6,300	5,000	5,900	–	5,900	5,300
	77°C		MPa	62.1	40.7	58.6	40.7	62.1	50.3	–	–	43.4	34.5	40.7	–	40.7	29.6
	250°F		psi	6,200	5,500	6,300	4,700	6,900	6,100	–	–	4,600	4,000	5,000	–	–	–
	121°C		MPa	42.7	37.9	43.4	32.4	47.6	42.1	–	–	31.7	27.6	34.5	–	–	–
	Yield Strength																
	−40°F	D 638	psi	16,500	16,000	17,000	16,100	18,700	17,000	–	–	–	–	–	–	13,600	13,500
	−40°C		MPa	113.8	110.3	117.2	111.0	128.9	117.2	–	–	–	–	–	–	93.8	93.1
	73°F		psi	12,000	8,500	12,400	8,600	13,100	9,000	14,200	–	8,800	7,500	–	–	8,800	7,400
	23°C		MPa	82.7	58.6	85.5	59.3	90.3	62.1	97.9	–	60.7	51.7	–	–	60.7	51.0
	170°F		psi	6,500	5,900	8,500	5,900	6,900	5,700	–	–	4,900	3,800	–	–	4,300	5,100
	77°C		MPa	44.8	40.7	58.6	40.7	47.6	39.3	–	–	33.8	26.2	–	–	29.6	35.2
	250°F		psi	4,800	4,000	5,100	4,700	5,000	4,400	–	–	3,300	3,000	–	–	–	–
	121°C		MPa	33.1	27.6	35.2	32.4	34.5	30.3	–	–	22.8	20.7	–	–	–	–
	Elongation at Break																
	−40°F (−40°C)	D 638	%	15	20	15	35	10	15	–	–	–	20	20	10	15	30
	73°F (23°C)		%	60	≥ 300	90	≥ 300	30	200	25	200	80	270	60	210	150	≥ 300
	170°F (77°C)		%	≥ 300	≥ 300	155	≥ 300	145	250	–	–	210	≥ 300	220	170	≥ 300	≥ 300
	250°F (121°C)		%	≥ 300	≥ 300	200	–	≥ 300	≥ 300	–	–	≥ 300	≥ 300	275	–	–	–
	Elongation at Yield																
	−40°F (−40°C)	D 638	%	4	–	–	5	5	5	–	–	–	–	–	–	8	14
	73°F (23°C)		%	5	25	5	30	5	25	–	–	–	–	–	–	7	40
	170°F (77°C)		%	30	30	30	30	25	30	–	–	–	–	–	–	30	40
	250°F (121°C)		%	45	40	30	30	45	40	–	–	–	–	–	–	–	–
	Shear Strength	D 732	psi	9,600	–	9,600	9,200	10,500	10,000	–	–	–	–	8,400	–	8,600	8,100
			MPa	66.2	–	66.2	63.4	72.4	68.9	–	–	–	–	57.9	–	59.3	55.8
STIFFNESS & CREEP	Flexural Modulus																
	−40°F	D 790	psi	470,000	500,000	470,000	500,000	510,000	–	–	–	410,000	480,000	285,000	340,000	340,000	400,000
	−40°C		MPa	3 241	3 447	3 241	3 447	3 516	–	–	–	2 827	3 309	1 965	2 344	2 344	2 758
	73°F		psi	410,000	175,000	410,000	175,000	430,000	190,000	440,000	180,000	285,000	160,000	245,000	125,000	295,000	180,000
	23°C		MPa	2 827	1 207	2 827	1 207	2 964	1 310	3 030	1 241	1 965	1 103	1 689	862	2 034	1 241
	170°F		psi	100,000	82,000	100,000	82,000	105,000	85,000	–	–	80,000	60,000	69,000	–	60,000	55,000
	77°C		MPa	689	565	689	565	724	586	–	–	552	414	476	–	414	379
	250°F		psi	78,000	60,000	78,000	60,000	80,000	–	–	–	50,000	50,000	–	–	48,000	44,000
	121°C		MPa	538	414	538	414	552	–	–	–	345	345	–	–	331	303
	Compressive Stress at 1% Deformation	D 695	psi	4,900	–	4,900	2,200	–	–	–	–	–	–	1,900	–	2,400	–
			MPa	33.8	–	33.8	15.2	–	–	–	–	–	–	13.1	–	16.6	–
	Deformation Under load[10]																
	2,000 psi 122°F	D 621	%	1.4	–	–	–	–	–	1.3	–	1.4	–	–	–	1.6	–
	13.8 MPa 50°C																
	Heat Deflection Temp.[4]																
	264 psi	D 648	°F	194	–	194	–	194	–	195	–	167	–	160	–	194	–
	1.8 x 10⁶ Pa		°C	90	–	90	–	90	–	90	–	75	–	71	–	90	–
	66 psi		°F	455	–	455	–	464	–	465	–	446	–	421	–	356	–
	05 x 10⁶ Pa		°C	235	–	235	–	240	–	240	–	230	–	216	–	180	–
TOUGHNESS	Brittleness Temp.	D 746	°F	−112	−85	−148	−121	−62	−62	–	–	−155	−120	–	–	−195	−165
			°C	−80	−65	−100	−85	−52	−52	–	–	−104	−84	–	–	−126	−109
	Izod Impact Strength																
	−40°F	D 256	ft. lb./in.	0.6	0.5	0.6	0.5	0.7	0.6	–	–	1.3	1.2	3.0	2.6	0.9	0.6
	−40°C		J/m	32	27	32	27	37	32	–	–	69	64	160	139	48	32
	73°F		ft. lb./in.	1.0	2.1	1.2	2.5	0.8	2.0	0.7	1.2	4.3	4.5	17	20	1.0	1.4
	23°C		J/m	53	112	64	133	43	107	37	64	230	240	907	1,068	53	75
	Tensile Impact Strength																
	Long Specimen 73°F	D 1822	ft. lb./in.²	240	700	255	–	–	–	–	–	252	800	280	550	291	450
	23°C		KJ/m²	504	1 470	536	–	–	–	–	–	550	1 680	588	1 155	611	945
	Short Specimen 73°F		ft. lb./in.²	75	110	–	–	–	–	–	–	90	126	–	–	73	101
	23°C		KJ/m²	157	231	–	–	–	–	–	–	189	265	–	–	153	213

GENERAL

Introduction

The invention of nylon by Du Pont in the early 30's, and its introduction in 1938, was truly a major breakthrough in polymer chemistry. No resin has yet been introduced that can begin to match the unique combination of properties which has made nylon the most versatile and broadly applied plastic material. Its use as an injection molding resin to produce a wide variety of engineering plastic parts used in every industry has grown, by some estimates, to the existence of more than a half million different parts, and the diversity and growth continues as the ZYTEL nylon resin product line expands through the results of ongoing extensive research and market development. Nylon has also found wide and varied uses as an extrusion resin for film, filament and proprietary oriented products. Finally, nylon is widely known for its multitude of uses in the textile fiber industry.

The information to follow is intended to help designers and engineers become familiar with the unique characteristics of the Du Pont nylon family of ZYTEL nylon resins and MINLON engineering thermoplastic resins, and how these characteristics are affected by environment and stress. With this knowledge, and the information provided by the Design Module, it is hoped that proper resin selection coupled with good design practice will result in the development of a successful part in the shortest possible time.

The data contained in this module falls within the normal range of product properties but should not be used to establish specification limits or used alone as the basis for design. Since Du Pont can make no guarantee of results and therefore assumes no liability in connection with the use of this information, confirmation of its validity and suitability should be obtained independently.

Product Overview

Basic ZYTEL Nylon Resins

The "basic" ZYTEL nylon resins include the unmodified nylon homopolymers and copolymers plus modifications produced by the addition of heat stabilizers, lubricants, ultraviolet screens, nucleating agents, etc. The majority of resins have molecular weights suited for injection molding and some are used for filaments, wire jacketing, film, and extruded shapes including rod, slab and sheet stock.

Many grades of ZYTEL nylon resin meet FDA requirements for food contact applications and are listed by the National Sanitation Foundation for potable water uses. Many are rated by Underwriters' Laboratories, Inc. for uses in electrical and electronic equipment. Many are certifiable to a long list of customer, military, and ASTM specifications.

66 Nylons

The oldest and still the most important of the nylon resins are ZYTEL® 101 and lubricated versions, 101 L and 101 F. These are 66 nylons made by the polymerization of hexamethylenediamine and adipic acid, each of which contain six carbon atoms. They have the highest melting point and dry-as-molded strength and stiffness of the melt processible nylon homopolymers. They possess an outstanding balance of properties – combining strength, moderate stiffness, high service temperature and a high level of toughness. They are particularly resistant to repeated impact, have low coefficients of friction and excellent resistance to abrasion. They resist fuels, lubricants and most chemicals, but are attacked by phenols, strong acids and oxidizing agents.

The 66 nylons are easily injection molded. The general purpose molding resins readily fill thin section molds due to low melt viscosity. These crystalline polymers set up rapidly, especially the nucleated and lubricated ZYTEL® 132 F and 133 L. The combination of easy fill and fast set up allows very fast molding cycles.

Nylons absorb moisture from the air and 66 nylon equilibrates at about 2.5% water at 50% RH and at about 8.5% at 100% RH. This plasticizes the nylon, somewhat lowering its strength and stiffness but increasing its toughness and elongation. Moisture absorption increases dimensions of 66 nylons by 0.006 in./in. at 50% RH and about 0.026 in./in. at 100% RH. The process is reversible, that is, the strength and stiffness increase and dimensions decrease as moisture content decreases. Absorption and desorption are slow processes. For example, it takes about 125 days for a .060" thick dry specimen to reach equilibrium moisture content when exposed to 50% relative humidity.

The ZYTEL nylon resins are not considered primary electrical insulators but their high temperature properties, their toughness and abrasion resistance, and their chemical resistance, combined with electrical properties adequate for most power frequencies and voltages, have made them the choice for a wide variety of electrical applications.

ZYTEL Nylon Resins for Extrusion

Du Pont offers a number of ZYTEL nylon resins specifically designed for extrusion. Although any of the unreinforced ZYTEL nylon resins may be extruded, the size, complexity and amenability to close control of dimensions is limited. For example, low viscosity molding resins, such as ZYTEL® 101 and ZYTEL® 151, may be extruded into filaments or on to wire but most film, tubing, and shape extrusion operations require a melt viscosity high enough to permit the unconstrained melt to solidify before it can deform.

Among the 66 nylons, this is provided by ZYTEL® 42, an unmodified 66 nylon of high molecular weight possessing all of the properties of ZYTEL® 101 – but surpassing this molding grade in several important aspects. It is significantly tougher and, in notch-free testing it ranks among the toughest of all nylon resins. Its higher molecular weight gives it higher elongation and better resistance to acids, zinc chloride and similar attacking reagents.

ZYTEL® 42HSB and ZYTEL® 45 HSB are heat stabilized versions. The latter has the most effective heat stabilizer system while the former meets FDA requirements for cooking films up to 1.2 mils in thickness.

The new 300 series of tubing resins offers a wide range of stiffness and other properties – all heat stabilized and embodying Du Pont's proprietary toughening technology. Those with a "P" suffix are plasticized.

ZYTEL® 301HS and 301PHS are 66 nylons. ZYTEL® 301HS is toughened but not plasticized, and has the highest tensile strength (8,000 psi dry/6,000 psi 50% RH), and melting point (491°F/255°C) of the 300 series. The plasticized version, ZYTEL® 301 PHS, is lower in tensile strength (4,800 psi dry/4,300 psi 50% RH) and modulus (110,000 psi dry/90,000 psi 50% RH) but otherwise retains many of the properties associated with 66 nylon.

ZYTEL® ST-350 PHS and ST-351 PHS are plasticized and toughened 612 nylons, with the latter having the higher level of plasticizer and, as a result, being lower in strength and stiffness. Both are supertough nylons combining intermediate flexibility with the chemical resistance and moisture insensitivity of their 612 nylon base. They are particularly useful in their resistance to zinc and calcium chloride solutions – which are representative of chemicals encountered in automotive uses.

ZYTEL® ST-811HS and 811PHS are supertough unextracted nylon 6 resins. Because of their base resin, these are the most flexible of the ZYTEL nylon resin line. Flexural modulus values are about 65,000 psi dry/40,000 psi 50% RH for ZYTEL® ST-811HS and 40,000 psi dry/30,000 psi 50% RH for ZYTEL® ST-811PHS.

ZYTEL Nylon Resins for Extrusion

Designation	Description	Characteristics & Major Uses
ZYTEL® 42	High Viscosity 66 Nylon	For unsupported extrusion into film, rod, tubing, and complex shapes and for specialty molding applications.
ZYTEL® 42 HSB	Heat Stabilized High Viscosity 66 Nylon	Heat stabilized version of ZYTEL® 42. Meets FDA requirements for cooking films at 1.2 mil thickness.
ZYTEL® 45 HSB	Heat Stabilized High Viscosity 66 Nylon	Maximum heat stabilization for ZYTEL® 42. Does not meet FDA requirements.
ZYTEL® 301 HS	Toughened Heat Stabilized 66 Nylon	For cable jacketing and small diameter tubing – especially automotive vacuum emission tubing.
ZYTEL® 301 PHS	Plasticized, Toughened, Heat Stabilized 66 Nylon	Plasticized version of ZYTEL® 301 HS. For convoluted tubing and cable jacketing.
ZYTEL® ST-350 PHS	Plasticized, Toughened, Heat Stabilized 612 Nylon	Flexible, "Supertough" resin. Superior resistance to zinc chloride, calcium chloride, and other automotive chemicals. Low moisture absorption. For hydraulic lines and other automotive tubing applications.
ZYTEL® ST-351 PHS	Plasticized, Toughened Heat Stabilized 612 Nylon	More flexible than ZYTEL® 350 PHS. Tailored for similar applications.
ZYTEL® ST-811 HS	Toughened, Heat Stabilized Nylon 6	Flexible, "Supertough" resin. For air conditioning, LP gas, and hydraulic hose and tubing.
ZYTEL® ST-811 PHS	Plasticized, Toughened Heat Stabilized Nylon 6	Most flexible, "Supertough" ZYTEL nylon resin for tubing and wire jacketing.
ZYTEL® 95 & ZYTEL® 96	Plasticized, Heat Stabilized Copolymers	Specialty automotive tubing and wire coating applications.

Glass Reinforced
ZYTEL
Nylon Resins

The Du Pont glass reinforced ZYTEL nylon resin family, often termed GRZ, extends the usefulness of nylon to applications requiring an elastic modulus of up to 1,600,000 psi and a tensile strength of up to 30,000 psi. And, by the use of various nylon matrices, essential characteristics of dimensional stability, toughness, chemical resistance, etc., can be maximized to meet the requirements of a wide range of applications.

Property enhancement is maximized by the uniform dispersion of specially treated glass fibers into the nylon. Treatment of the glass fibers produces a tightly adhering chemical bond between the nylon and the glass that enhances both tensile strength and stiffness over a wide range of environmental conditions. Glass levels over 50% are possible but Du Pont's experience is that 13, 33, and 43% loadings, in the different matrices, cover substantially all the needs. The highest loadings, of course, provide the highest strength and stiffness.

ZYTEL® 70G, in 13, 33, and 43% glass loadings is 66 nylon – with a lubricant added for improved machine feed and mold release properties. These have the highest strength, stiffness, creep resistance, and melting point. They may be pigmented and stabilized against the effects of long term high temperature exposure (HS-L) and hydrolysis (HR-L). They are priced lower than the

Part Weight

Monitoring part weight is an easy means of checking on the uniformity of a molding operation. Variations may indicate changes in part dimensions or properties.

Physical Tests

Practical test on molded or extruded parts are highly recommended. These are usually, but not necessarily, of the impact type. Energy-to break testing provides a means of measuring the energy required to break a part when it is struck in a carefully defined way – most meaningful if it simulates critical conditions encountered in installation or service. Impact testing can also be used simply to establish that degradation of the resin has not occured in the molding operation. Other physical tests such as flexing or stretching, etc., are used and are most often related to end use.

All tests of this type, of course, require careful control of moisture content and temperature as well as the more obvious mechanical elements.

It should also be noted that these comments on end-use testing are intended only to make the reader aware of its possibilities. Details have to be worked out for each case with the help of appropriate texts on testing and quality control.

Relative Viscosity (ASTM D 789)

Relative viscosity, a solution viscosity related to molecular weight, is also a useful measure of the quality of a nylon part. Toughness is a function of molecular weight. A substantial reduction of relative viscosity below that of the ZYTEL composition used is indicative of poor processing and may cause reduced toughness. Thus, this test often appears in end user specifications. For accurate results, careful laboratory procedures and practices are necessary. A physical test to establish the desired toughness level is always preferable.

Appearance

Some of the factors affecting appearance are also related to toughness and other elements of quality. Ideally, a part should be without splay, burn marks, flash, sinks, voids, contamination, unmelted particles and visible weld lines. Some judgment is obviously required as these characteristics are difficult to express on a quantitative basis, and some, such as flash, sinks and voids *may* not impair function. The surface finish can be described and may be included.

Use of standards with numerical ratings and showing acceptable and nonacceptable parts are useful in obtaining consistent evaluations.

Government and Agency Approval

Regulatory Considerations

In some applications, the material used must be approved by or meet the requirements of various government and private agencies. The list of resins qualified in this respect changes frequently. Du Pont will provide the current status of specific regulations with respect to any member of the nylon family of engineering resins on request.

Agencies Regulating Safety

United States Department of Health and Human Services – Food and Drug Administration

Federal law, most notably the Food Additives Amendment of 1958 to the Food, Drug & Cosmetic Act, assigns to the FDA wide powers in the regulation of substances added to food. Of most concern to the Plastics Industry are "indirect additives," e.g., those substances capable of migrating into the food from a contacting plastic material.

A number of ZYTEL nylon resins are in full compliance with the safety clearance issued by the FDA as 21 CFR 177.1500 and may safely and legally be used in food packaging, handling and processing applications. These include ZYTEL® 101 NC-10, the lubricated version ZYTEL® 101 L NC-10, ZYTEL® 42 NC-10 and certain other commercially and experimentally coded resins. The 612 nylons such as ZYTEL® 151 and 158 are permitted for repeated use applications up to 100°C (212°F).

March 16, 1992

Mr. Denis Dorsey
Bioteque America, Inc.
51 Rainlily road
Levittown, PA. 19056

Dear Denis:

Enclosed are the references for answering your submission questions. Your product will be sterilized with 100 % ethylene oxide as outlined in the AAMI guideline ST27-1988. The product will have a sterility assurance level of one times ten to the six. This is the accepted SAL for medical devices which contact open wounds or is used in the operating theater. The product residual levels depend on the device use. The guidelines for residuals were outlined in 1978 in the Federal Register. If you have any further questions please call.

Dave Vogel

Dave Vogel

Laboratory Manager

210

Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices

ST27

Process Design, Validation, Routine Sterilization, and Contract Sterilization

Developed by
Association for the Advancement of Medical Instrumentation

Approved 31 March 1988 by
American National Standards Institute

Abstract: This guideline provides the essential elements of good operating practice for ethylene oxide (EO) sterilization of medical devices. It addresses sterilization process development and validation, and the control of routine EO sterilization.

Contents

SECTION	PAGE
Committee Representation	v
Foreword	vii
1. Scope	1
2. Applicable Documents	1
3. Product and Package Considerations	1
4. Sterilization Process Development	2
4.1 General	2
4.2 Equipment Selection	2
4.2.1 Preconditioning (outside EO Chamber)	2
4.2.2 EO Exposure Chamber	2
4.2.3 Instrument Performance	3
4.2.4 Chamber Input and Exhaust Controls	3
4.2.5 EO Aeration Facilities	3
4.2.6 Safety and Health	4
4.3 Cycle Development—Physical Parameters	4
4.3.1 Preconditioning (Outside EO Chamber)	4
4.3.2 EO Chamber Cycle Development	4
4.4 Cycle Development—Microbiological Considerations	5
4.4.1 General	5
4.4.2 Microbial Challenge System	5
4.4.3 Microbial Challenge Procedures	6
4.4.4 Development Studies Using Microbial Challenge—Overkill Method	6
4.4.5 Development Studies Using Microbial Challenge—Combined Biological Indicator/Bioburden Method	6
4.4.6 Development Studies Using Microbial Challenge—Absolute Bioburden Method	7
4.4.7 Cycle Selection Criteria	7
4.5 Cycle Development—Equivalency or Adoption	8
4.6 Product Functionality Tests	8
4.7 Poststerilization Product Aeration	8
5. Sterilization Process Validation	8
5.1 General	8
5.2 Installation Qualification	9
5.3 Performance Qualification	10
5.4 Certification	10
6. Manufacturing (Routine EO Sterilization)	10
6.1 General	10
6.2 EO Sterilization Process Control	10
6.3 Process Control Release	11
6.4 Microbiological Testing Guidelines	11
6.4.1 Bioburden Monitoring	11
6.4.2 Microbial Challenge	11
6.4.3 Biological Indicator Release of Sterilized Products	11
6.5 Reprocessing	11
6.6 Maintenance of Validation	11
6.6.1 General	11
6.6.2 Change Control Procedure	11
6.6.3 Qualification of Process, Equipment, Product, or Package Changes	12
6.6.4 Periodic Requalification	12
6.7 Operational Practices	12
6.7.1 Personnel	12
6.7.2 Audit of Operations	12
6.7.3 Calibration	12
6.7.4 Maintenance	12
6.7.5 EO Leaks and Spills	12

PAGE

SECTION

7. Contract Sterilization 12
   7.1 General 12
   7.2 Validation of Sterilization Process 12
   7.3 Product Load Configuration 13
   7.4 Process Control 13
   7.5 Indicators and Test Samples 13
   7.6 Control of Changes and Process Deviations 13
   7.7 Resterilization 13
   7.8 Materials Handling and Documentation 13

8. Glossary 14

9. References 16

Appendix A: Rationale for the Development and Provisions of This Guideline 17

Appendix B: Packaging Validation and Control 19

Appendix C: Calculation of EO Concentrations 7

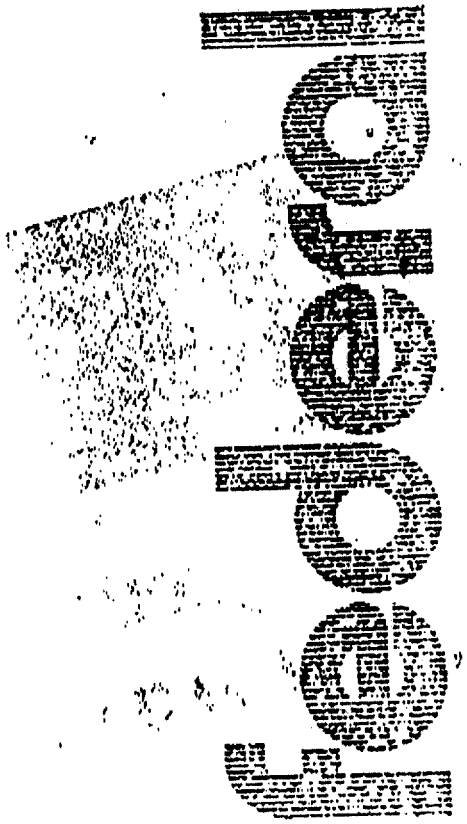
Figures
   Figure 1. Overkill Method of EO Cycle Development 8
   Figure 2. Combined Biological Indicator/Bioburden Method or Absolute Bioburden Method of EO Cycle Development 9
   Figure 3. Validation Program .....

ST27

283

C. W. Woscinski

FRIDAY, JUNE 23, 1978
PART V



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

ETHYLENE OXIDE, ETHYLENE CHLOROHYDRIN, AND ETHYLENE GLYCOL

Proposed Maximum Residue Limits and Maximum Levels of Exposure

284

Ethylene oxide: ...
Ethylene chlorohydrin, 16 μg/kg/day/30 days
Ethylene glycol, 2.5 mg/kg/day/30 days

A product which complies with paragraph (a) of this section shall also comply with the limits set forth in this paragraph.

PART 821—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICAL DEVICES: STERILE DEVICES

2. By adding a new Part 821 consisting of one section to read as follows:

Sec.
821.100 Maximum residue limits for ethylene oxide, ethylene chlorohydrin, and ethylene glycol.

AUTHORITY: Secs. 513-521, 701, 52 Stat. 1055-1056 as amended, 90 Stat. 540-574 (21 U.S.C. 360c-360k, 371).

§ 821.100 Maximum residue limits for ethylene oxide, ethylene chlorohydrin, and ethylene glycol.

(a) Each medical device for human use of a type listed in this paragraph for which ethylene oxide is used as a sterilant in the manufacture of the finished device, its component parts, or its market container shall not, when tested as packaged in its market container, exceed the following residue levels:

(Parts per million)

Medical device	Ethylene oxide	Ethylene chlorohydrin	Ethylene glycol
Implant:			
Small (<10 grams)	250	250	5,000
Medium (10-100 grams)	100	100	2,000
Large (>100 grams)	25	25	500
Intrauterine device	5	10	10
Intraocular lenses	25	25	500
Devices contacting mucosa	250	250	5,000
Devices contacting blood (ex vivo)	25	25	250
Devices contacting skin	250	250	5,000
Surgical scrub sponges	25	250	500

(b) Any medical device for human use failing to comply with the requirements of paragraph (a) of this section shall not be released for marketing.

(c) Each manufacturer of a medical device for human use subject to this section shall prepare a residue dissipation curve for each manufacturing procedure in which ethylene oxide is used as a sterilant for the device, its component parts, or its market container.

288

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

APR 29 1992

Mr. Denis Dorsey
Bioteque America, Inc.
51 Rainlily Road
Levittown, Pennsylvania 19056-2301

RE: K920633
Nichols Vaginal Stent
Dated: December 27, 1991
Received: February 12, 1992

Dear Mr. Dorsey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following information:

Device Description

1. Provide a complete description of your device including its design, dimensions, physical properties, surface characteristics, etc. Also, provide detailed schematics of your device. Compare these technological characteristics of your device to a legally marketed device.

2. Provide the chemical and physical specifications for the material from which your device is made.

Toxicity Data

3. Provide mucosal irritation, sensitization, acute and chronic toxicity data conducted on your final product to support its safe use. Please refer to the enclosed "Tripartite Biocompatibility Guidance for Medical Devices" for further information.

Sterilization

4. Provide a description of the method that will be used to validate the sterilization cycle.

5. Identify the sterility assurance level that your firm intends for your device.

6. Provide a description of the packaging system used to maintain device sterility.

7. Identify the maximum levels of residues of ethylene oxide, ethylene

chlorohydrin and ethylene glycol for your device.

Device Labeling

8. Provide complete professional and patient labeling which includes indications for use, contraindications, precautions, warnings, adverse reactions and instructions for use (see enclosure). The following specific revisions should be incorporated into your labeling:

   a. Provide specific indications for use for your device which describe the clinical conditions for which the device is intended (e.g., post-operative use after reconstructive surgery to help prevent vaginal contracture).

   b. Include recommended device wear-times, cleaning instructions and compatible lubricants with your instructions for use.

9. Delete all exaggerated claims of safety and effectiveness from your professional and patient labeling, for example "will keep the vaginal cavity from excessive scarring" and "will simulate protective vaginal secretions."

The additional information should be submitted in duplicate, referencing the 510(k) number above to:

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

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations.

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days, it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

If you have any questions concerning the contents of this letter, please contact Ms. Christine L. Brauer, at (301) 427-1180. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number 1-800-628-2041 or at (301) 443-6597.

Sincerely yours,

Mark Kramer for

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

2888

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-92-0633

4/29/92

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
BIOTEQUE AMERICA, INC. ATTN: DENIS DORSEY 51 RAINLILY ROAD LEVITTOWN, PA 19056	01/27/92	02/12/92	05/12/92
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K920633
	PHONE NO: 215-946-1774		
SHORT NAME: BIOTAMER	ESTABLISHMENT NO: 2529577		

TO:	
ODE/DMC	CONT. CONF.: N STATUS : H REV PANEL : OB PAN/PROD CODE(S): OB/ / /

SUBJECT:
NICHOLS VAGINAL STENT

DECISION:	RQST INFO DATE: 04/29/92	INFO DUE DATE: 05/29/92
DECISION DATE: / /	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /

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290

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291

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Sincerely yours,

MM for LY

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosurescc:

HFZ-401
HFZ-470
DO
Final: JAL/4.24.92

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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z-470	Brauer	4/24/92						
Z-470	Tillman c.f.	4/24/92						
HFZ-470	Kramer for	4/27/92						

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date: April 23, 1992

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

Subject: 510(k) NOTIFICATION K920633

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.

Consult in Gene when AI received.

X (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

X Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

_____

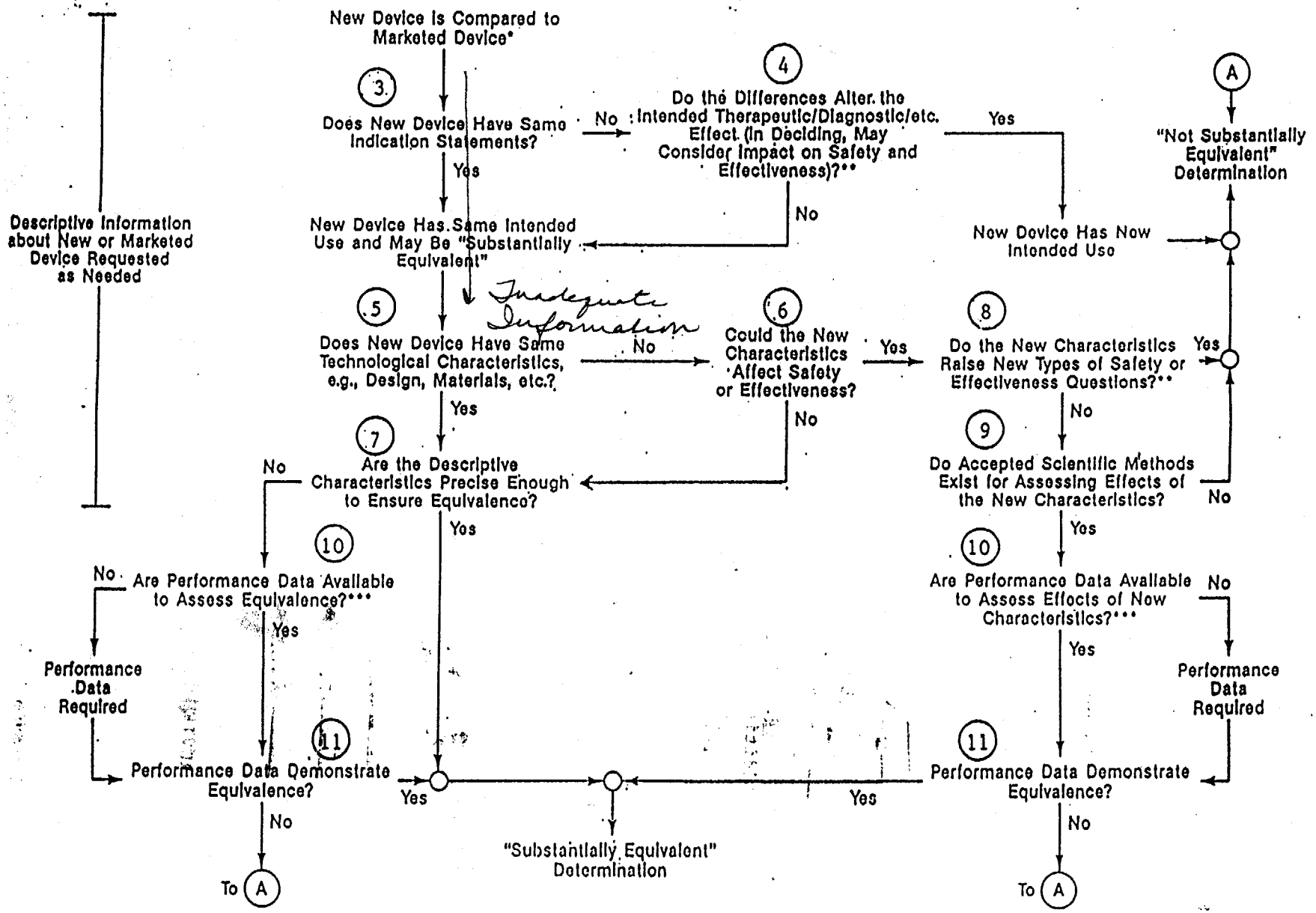
Additional Product Code(s) w/Panel (optional):

_____

REVIEW: MRT for Colin Pollard (BRANCH CHIEF) | OGDB (BRANCH CODE) | 4/24/92 (DATE)

FINAL REVIEW: Mark Kramer for LYin (DIVISION DIRECTOR) 4/29/92 (DATE)

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests

** This Decision Is Normally Based on Descriptive Information Alone, But

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

Document Control Number: K920633
Login Date: 02/12/92
90 Day Due Date: 05/12/92
Reviewer: Microbiologist
Division/Branch: DRAERD/OGDB

Applicant and Contact: Bioteque America, Inc.
Attn: Mr. Denis Dorsey
51 Rainlily Road
Levittown, PA 19056-2301

Trade Name: Nichols Vaginal Stent
Common Name: Vaginal Stent

Product To Which Compared: Counseller Plastic Mold

	YES	NO	
1. IS PRODUCT A DEVICE?	X	___	IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	X	___	IF NO STOP
3. SAME INDICATION STATEMENT?	X	___	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 NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	___	___	IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	___	___	IF YES STOP -> SE IF NO GO TO 10
8. NEW TYPES OF SAFETY AND EFFECTIVENESS QUESTIONS	___	___	IF YES STOP-> NSE
9. ACCEPTED SCIENTIFIC METHODS EXIST	___	___	IF NO STOP-> NSE
10. PERFORMANCE DATA AVAILABLE	___	___	IF NO REQUEST DATA
11. DATA DEMONSTRATE EQUIVALENCE	___	___	

295

NARRATIVE DEVICE DESCRIPTION

1. Intended Use:

Vaginal stents are class II medical devices intended for use to support the vagina, hold a skin graft and prevent contracture after reconstructive surgery.

2. Device Description:

	YES	NO
Is the device life-supporting or life sustaining?	___	X
Is the device implanted (short-term or long-term)?	X	___
Does the device design use software?	___	X
Is the device sterile?	X	___
Is the device single use?	___	X
Is the device home use?	X	___
Is the device for prescription?	X	___
Does the device contain a drug or biological product as a component?	___	X
Is this device a kit?	___	X

Device Description and Comparison to a Predicate Device

The Nichols Vaginal Stent, which is made from polyethylene, is available in three sizes and two designs which allow drainage. The sizes are listed below.

1. Length - 11.25 centimeters (cm)
   Diameter - 3.75 cm
   Circumference - 11.78 cm

2. Length - 13.38 cm
   Diameter - 4.17 cm
   Circumference - 13.1 cm

3. Length - 15.5 cm
   Diameter - 4.77 cm
   Circumference - 15 cm

One design consists of a solid polyethylene oblong device with a 1 cm hole through the device. The other design consists of a polyethylene oblong hollow device with a 4.75 millimeter wall thickness with two 1 cm holes at each end.

The chemical and physical specifications of the materials of the device have not been provided. A complete description of the device has not been provided either. For example, the patient's instructions for use indicate that one area of the device has a flattened surface. This is not clearly indicated on the device diagrams. The technological characteristics of the device need to be compared to a predicate device. A vaginal stent has not been cleared through the 510(k) process although the devices were classified (21 CFR 884.3900).

Biocompatibility Data

Vaginal stents contact vaginal and cervical tissue, and are used for several months following surgery. Vaginal stents, therefore, can be considered long-term implants. No toxicity data were provided in the 510(k). Mucosal irritation, sensitization, acute and chronic toxicity data should be provided to support the safe use of the device.

Sterility

The device is provided sterile, and information on the sterilization cycle should be provided.

Device Labeling

(b) (4)

[redacted]

3. Recommendation:

The following information should be requested:

Device Description

1. Provide a complete description of your device including its design, dimensions, physical properties, surface characteristics, etc. Also, provide detailed schematics of your device. Compare these technological characteristics of your device to a legally marketed device.

2. Provide the chemical and physical specifications for the material from which your device is made.

Toxicity Data

3. Provide mucosal irritation, sensitization, acute and chronic toxicity data conducted on your final product to support its safe use. Please refer to the enclosed "Tripartite Biocompatibility Guidance for Medical Devices" for further information.

Sterilization

4. Provide a description of the method that will be used to validate the sterilization cycle.

5. Identify the sterility assurance level that your firm intends for the device.

6. Provide a description of the packaging system used to maintain device sterility.

7. Identify the maximum levels of residues of ethylene oxide, ethylene chlorohydrin and ethylene glycol for your device.

Device Labeling

8. Provide complete professional and patient labeling which includes indications for use, contraindications, precautions, warnings, adverse reactions and instructions for use (see enclosure). The following specific revisions should be incorporated into your labeling:

   a. Provide specific indications for use for your device which describe the clinical conditions for which the device is intended (e.g., post-operative use after reconstructive surgery to help prevent vaginal contracture).

   b. Include recommended device wear-times, cleaning instructions and compatible lubricants with your instructions for use.

9. Delete all exaggerated claims of safety and effectiveness from your professional and patient labeling, for example "will keep the vaginal cavity from excessive scarring" and "will simulate protective vaginal secretions."

Christine Brauer

Christine Brauer

Date: April 23, 1992

MRT for Colin Pollard

Chief, Branch

Date: 4/24/92

Concur / X /

Do Not Concur / /

298

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

FEBRUARY 19, 1992

BIOTEQUE AMERICA, INC.
ATTN: DENIS DORSEY
51 RAINLILY ROAD
LEVITTOWN, PA 19056

510(k) Number: K920633
Received: 02-12-92
Product: NICHOLS VAGINAL STENT

We have 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. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date, you may want to check with FDA to determine the status of your submission.

In addition, the SMDA 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 manufacturers 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**

899

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 a 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.

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 Ms. Anita Rayner at (301) 443-7120.

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.

200

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
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K920633

BIOTEQ

Bioteque America, Inc.
contact: Denis Dorsey
51 Rainlily Road
Levittown, PA. 19056-2301
(215) 946-1774

k920633

December 27, 1991

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

Re: 510(k) Notification

Attention: Document Mail Clerk

This is to notify you of the intention by Bioteque America, to market the following device:

Classification Name: Vaginal Stent.
Common Name: Stent.
Proprietary Name: Nichols Vaginal Stent

Establishment Registration Number: 2529577

Classification: Vaginal Stent would most likely be reviewed by the FDA Obstetrics and Gynecology Device Panel. The classification number is 85HFK and is listed as a class 2 device.

Performance Standards: Not applicable.

Label/Labeling/Promotional Material: Draft copies of the package and box labeling, drawings and labeled specimen are enclosed.

Substantial Equivalence: The Nichols Vaginal Stent is similiar in design and function to the Counseller-Type plastic mold. Only a picture of this model was available.

We consider our intent to market our device as confidential information and request the FDA consider it as such. We have not disclosed the intent to market this device and have taken precautions to protect this confidentiality. Please do not hesitate to contact me at (215)946-1774 if I can answer any questions in regards to this submission.

Sincerely yours,

Denis Dorsey

Denis Dorsey.

Enclosures

PRODUCT FORM:

TRADE NAME: Nichols Vaginal Stent.
CLASSIFICATION: Vaginal Stent.

Class - 2.
Classification Number - 85~~HFK~~. KXP
Regulation Number - 884.3900.

SPECIFICATIONS: See drawings Ahoka America #N122791, N122791A, N122791B.

3 Sizes. Length, Diameter, Circumferance.

Product Number	Size
NVS1	L 11.25cm, D 3.75cm, C 11.775cm. (1.4")
NVS2	L 13.375cm, D 4.17cm, C 13.1cm. (1.6")
NVS3	L 15.5cm, D 4.77cm, C 15cm. (1.88")

MATERIALS: Medical grade polyethelene. - ? chemical/physical specs
Biocompatibility Data -

PACKAGING: Individually packed in polybags or one per box.

Contents per pack/box.
1 - Vaginal Stent.
1 - Instructions.

Pack/box label.
Universal stick-on label.

Contents per case.
9 pack/box.

Case label.
Universal stick-on label.

STERILIZATION: ETO. → sterilization info

Contractor - Griffith Micro Science, Bound Brook, NJ. 08805
Scott Salley- ETO Consultant.

204

PROMOTIONAL MATERIAL:

NICHOLS VAGINAL STENT

picture

Bioteque product # NVS1 Small
NVS2 Medium
NVS3 Large

Purpose: To prevent unwanted contraction of the vagina.

Indications: To distend the vaginal canal during the postoperative phase.

? NO

Distributed by: BIOTEQ
Bioteque America, Inc.
Levittown, PA. 19056-2301.

305

Indications/use – post operative or intraoperative
Contraindications
Precautions
Warnings
Adverse Rxns
Instructions for use

INSTRUCTIONS TO THE PHYSICIAN:

Following the construction of a neovagina or any portion thereof, or following a vaginalplasty operation performed to enlarge a small vagina, it is usually desirable to distend the vaginal canal during the postoperative healing phase with a device to prevent unwanted contraction of the scar. Such an obturator should be simple, smooth surfaced, light in weight, sterilized, capable of removal and reinsertion by the patient, and affordable. It should be available in various sized comparable to those of the erect penis. Since even a plastic obturator is a foriegn body in the vagina, it will likely stimulate protective vaginal secretions and a route through the obturator for drainage from the vault of the vagina is desirable.

NO

Claim Basis?

This plastic obturator designed and produced in various sizes, meets the above criteria.

Instructions courtesy of David H. Nichols, M.D.

200

INSTRUCTIONS TO THE PATIENT:

Your doctor has recognized the need for wearing a device or obturator within the vagina that will keep the vaginal cavity from excessive scarring and contraction during its healing phase. When the obturator is in place you may be concious of a mild feeling of pressure, but there should be no pain. (Should the device become painful, bring the matter promptly to your physician's attention). There is a small knob at the outside end of the obturator that can be grasped to facilitate its insertion and removal.

When inserting the obturator your pelvic muscles must be relaxed. With one hand separate the labia minora and with the other insert the blunt end of the well lubricated obturator into the vaginal cavity and gently make pressure, pushing the obturator into the vagina until it stops and the end knob is comfortably within the vagina. The obturator should be turned so that one flattend surface near the tip will come to rest beneath the ureathra, (which is the external opening into the bladder), minimizing pressure in that sensitive area. It may be retained and replaced more easily if you wear a supportive sanitary napkin when the obturator is in place.

The obturator should be removed from time to time, as your physician will instruct, washed with soap and water and replaced.

Instructions courtesy of David H. Nichols, M.D.

SUMMARY:

The safety and effectiveness of this Vaginal Stent has not changed. Also, the materials and intended use of this device does not differ from the materials and intended use of marketed devices within the same type. Any changes in the labeling are immaterial to the safety and effectiveness issues. Any additional information will be made available upon request.

Address all inquires to:

Bioteque America
contact: Denis Dorsey
51 Rainlily Road
Levittown, PA. 19056-2301
(215) 946-1774

(b) (4) Drawing

(b) (4) Drawing

NICHOLS VAGINAL STENT

#NVS1

to prevent unwanted contraction of the vagina.

CAUTION:Federal law restricts this device to sale by or on the order of a physician. please refer to instructions prior to use.

Manufactured exclusively for:
BIOTEQUE AMERICA, INC.
Levittown, PA. 19056-2301.

NICHOLS VAGINAL STENT

#NVS2

to prevent unwanted contraction of the vagina.

CAUTION:Federal law restricts this device to sale by or on the order of a physician. please refer to instructions prior to use.

Manufactured exclusively for:
BIOTEQUE AMERICA, INC.
Levittown, PA. 19056-2301.

NICHOLS VAGINAL STENT

#NVS3

to prevent unwanted contraction of the vagina.

CAUTION:Federal law restricts this device to sale by or on the order of a physician. please refer to instructions prior to use.

Manufactured exclusively for:
BIOTEQUE AMERICA, INC.
Levittown, PA. 19056-2301.

UNIVERSAL "STICK ON LABEL FOR BOXES AND CASES

"product description here"

MANUFACTURED EXCLUSIVELY FOR
BIOTEQUE AMERICA

caution: Federal law restricts the sale of this device by or on the order of a physician

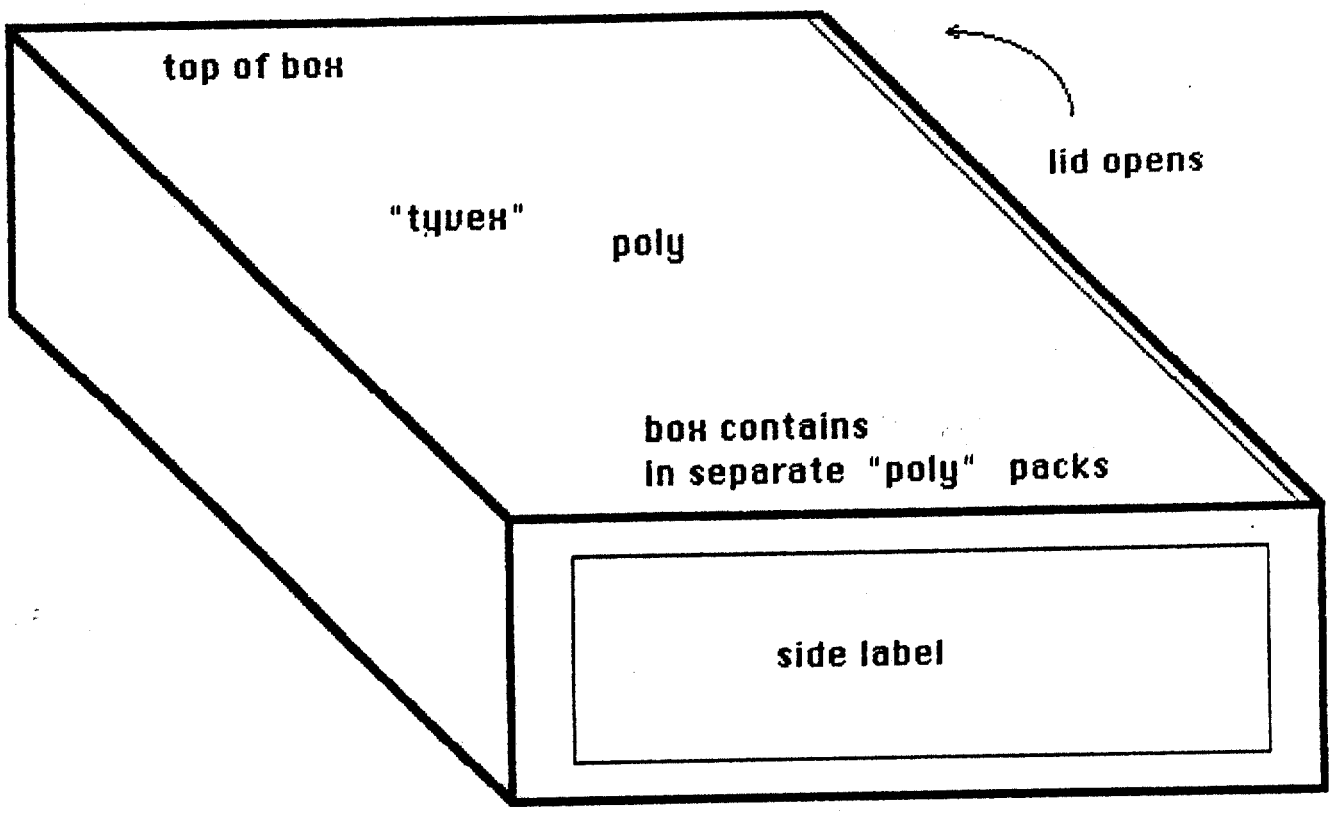
CONTENTS:

BIOTEQUE AMERICA - LEVITTOWN, PA

LOT # 92 BA012292

patent pending

3/8



SIDE LABEL

MANUFACTURED EXCLUSIVELY FOR
BIOTEQUE AMERICA

caution: Federal law restricts the sale of this device by or on the order of a physician

CONTENTS:

PATENT PENDING

BIOTEQUE AMERICA - LEVITTOWN, PA

TOP OF BOX

BIOTEQUE AMERICA

313