

CT - 6 132

Summary of Safety and Effectiveness

Description

OPTISOL-GS Corneal Storage Media is substantially equivalent in both intended use and formulation to our currently marketed OPTISOL Corneal Storage Media (K894162). Like our currently marketed OPTISOL Corneal Storage Media, OPTISOL-GS Corneal Storage Media is used for storage of donor cornea, after harvesting, until transplantation into a recipient. The OPTISOL-GS formulation is almost identical to our OPTISOL formulation, the only difference is that the OPTISOL-GS formulation additionally contains 200 µg/mL of streptomycin. Both OPTISOL and OPTISOL-GS contain gentamicin sulfate as an antimicrobial agent. The addition of streptomycin in OPTISOL-GS provides additional coverage against gentamicin-resistant bacteria.

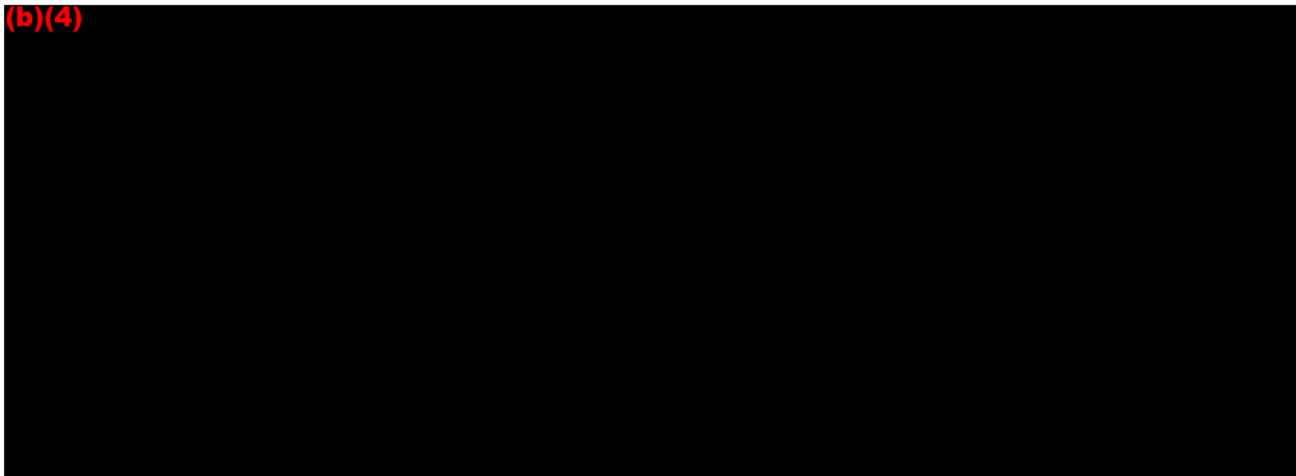
Manufacturing/Stability

(b)(4)



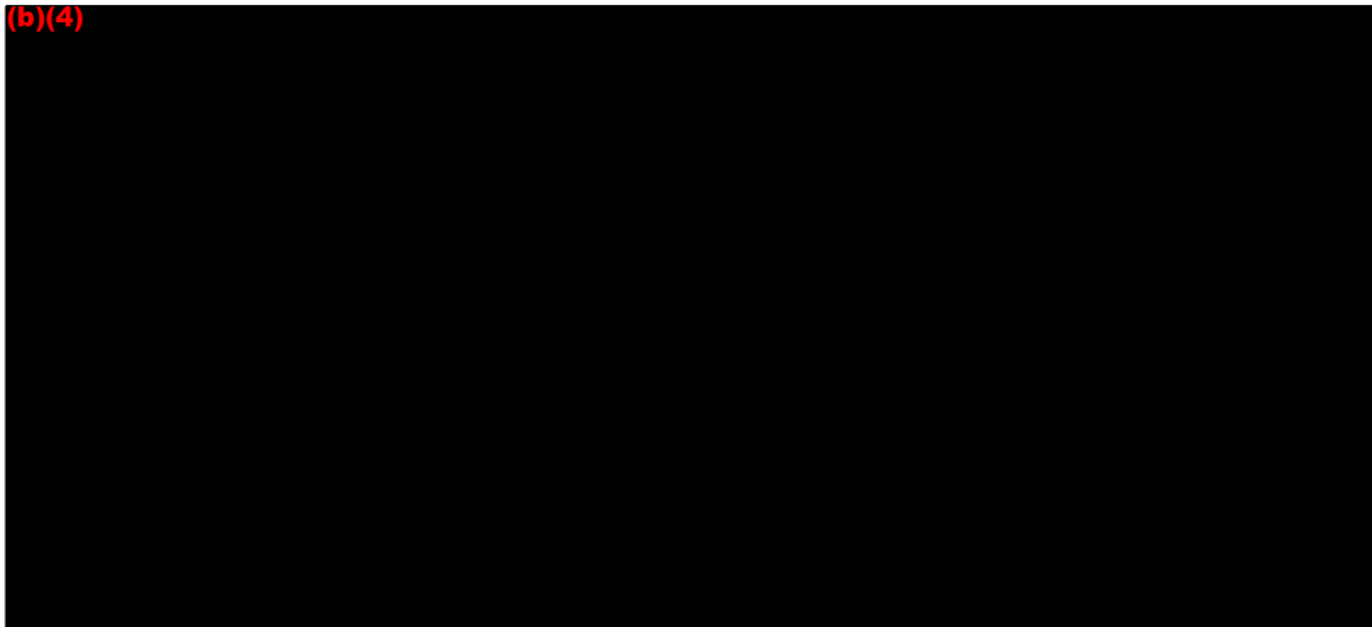
Preclinical Studies

(b)(4)



Clinical Studies

(b)(4)





RECEIVED

17 MAY 94 09 14

FDA/CDRH/OCE/DMC

May 13, 1994

Food & Drug Administration
Center for Devices & Radiological Health
PMA Document Mail Center HFZ-401
1390 Piccard Drive
Rockville, MD 20850

This letter serves as official notification to the Food & Drug Administration of the formal change of Chiron Vision's official correspondent to Judy F. Gordon, D.V.M., Vice President, Scientific Affairs for the following approved 510 (k) Notifications:

Product Name

Filing Number

(b)(4)

A large black rectangular redaction box covers the majority of the page content below the headers. The text "(b)(4)" is printed in red at the top left corner of this box.

A handwritten signature, possibly "J. Gordon", is written in black ink.

9342 Jeronimo Road, Irvine, CA 92718-1903 • TEL: 714-768-4690 • FAX: 714-768-4882

For customer service inquiries, please call 800-843-1137.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

May 11, 1994
page 2

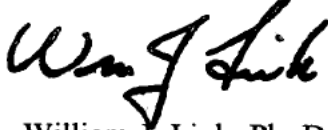
(b)(4)



If you have any questions, or require further clarification, please contact our office at (800) 553-3354, extension 341.

Sincerely,

CHIRON VISION CORPORATION



William J. Link, Ph. D.
Chairman & Chief Executive Officer



CHIRON



IntraOptics

October 25, 1993

Food & Drug Administration
Center for Devices & Radiological Health
PMA Document Mail Center, HFZ-401
1390 Piccard Drive
Rockville, MD 20850

RECEIVED
27 OCT 93 10 48
FDA/CDRH/OCE/DNC

Reference: 510(k) Notification #K924165
Optisol-GS Corneal Storage Media

Dear Sir or Madam:

This letter serves as official notification to the Food & Drug Administration of the formal name change of our firm from Chiron IntraOptics, Inc. to Chiron Vision Corporation.

Please direct all future communications to Chiron Vision Corporation, 9342 Jeronimo Road, Irvine, California 92718, as they apply to 510(k) Notification #K924165.

The designated official correspondent for this file is Carol L. Patterson, Senior Director of Regulatory Affairs and Quality Compliance.

If you have any questions, or require further clarification, please contact our office at (800) 553-3354, extension 327.

Sincerely,

A handwritten signature in dark ink, appearing to read "Wm J Link", is written over a horizontal line.

William J. Link, Ph.D.
Chairman & Chief Executive Officer
Chiron Vision



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT - 6 1992

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Ms. Carol L. Patterson
Director, Regulatory Affairs/
Quality Compliance
Chiron IntraOptics, Inc.
9342 Jeronimo Road
Irvine, CA 92718-1903

Re: K924165
Trade Name: OPTISOL-GS Corneal Storage Media
Regulatory Product Class: Unclassified
Dated: August 17, 1992
Received: August 19, 1992

Dear Ms. Patterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, and 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. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a 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 on the labeling for your device, please contact the Division of Compliance Operations, Device Labeling Compliance Branch (HFZ-326) at (301) 427-1342. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Nancy C. Brogdon
Interim Director
Division of Ophthalmic Devices
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)

KARAM V. BATRA, Ph.D.

Subject

510(k) NOTIFICATION

K924/65

To

THE RECORD

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

- ☒ (A) Is substantially equivalent to marketed devices: *ie. 9/17/92*
- ☐ (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:

86 LYX

UNCLASSIFIED

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

REVIEW:

(BRANCH CHIEF)

DSDB Z464
BRANCH CODE9/18/92
(DATE)

FINAL REVIEW:

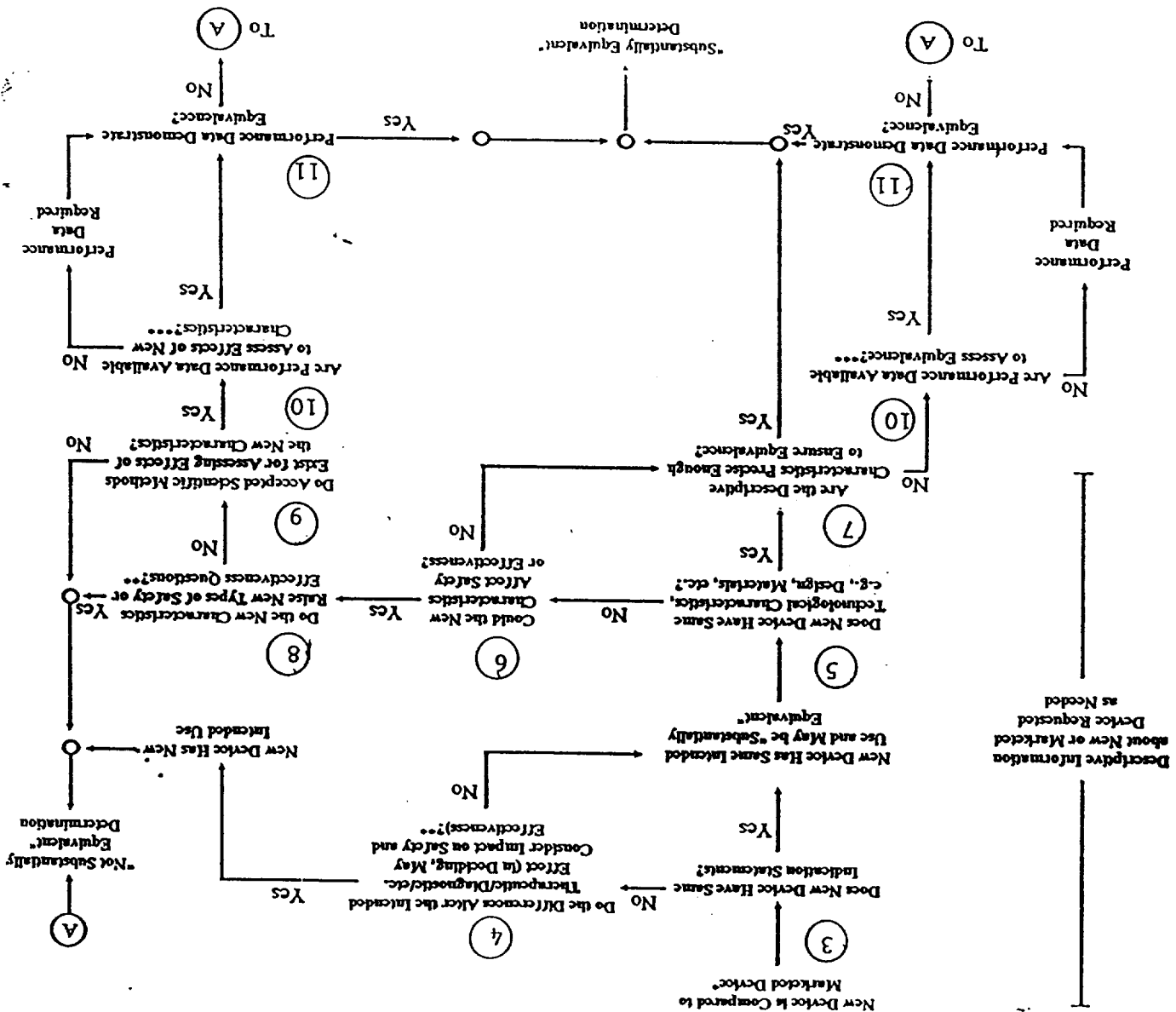
(DIVISION DIRECTOR)

10-7-92
9-28-92
(DATE)

the file on the cited predicate device indicates it is UNCLASSIFIED.

Wm 9/28/92

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.

-K 924165 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: K. BATRA DIVISION/BRANCH: DOD/DSDB
 TRADE NAME: OPTISOL-GS COMMON NAME: Corneal Storage Media
CORNEAL STORAGE MEDIA
 PRODUCT TO WHICH COMPARED: K 894162 Chiron OPTISOL CORNEAL STORAGE
 (510(k) NUMBER IF KNOWN) K 883854 Chiron DEXAL " " " " MEDIA

YES	(NO)
-----	------

1. IS PRODUCT A DEVICE?

✓	
---	--

- IF NO STOP

2. DEVICE SUBJECT TO 510(k)?

✓	
---	--

- IF NO STOP

3. SAME INDICATION STATEMENT?

✓	
---	--

- IF YES GO TO 5

4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?

--	--

- IF YES STOP - NE

5. SAME TECHNOLOGICAL CHARACTERISTICS?

✓	
---	--

- IF YES GO TO 7

6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?

--	--

- IF YES GO TO 8

7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?

✓	
---	--

- IF NO GO TO 10
- IF YES STOP - SE

8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?

--	--

- IF YES STOP - NE

9. ACCEPTED SCIENTIFIC METHODS EXIST?

--	--

- IF NO STOP - NE

10. PERFORMANCE DATA AVAILABLE?

--	--

- IF NO REQUEST DATA

11. DATA DEMONSTRATE EQUIVALENCE?

--	--



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

4

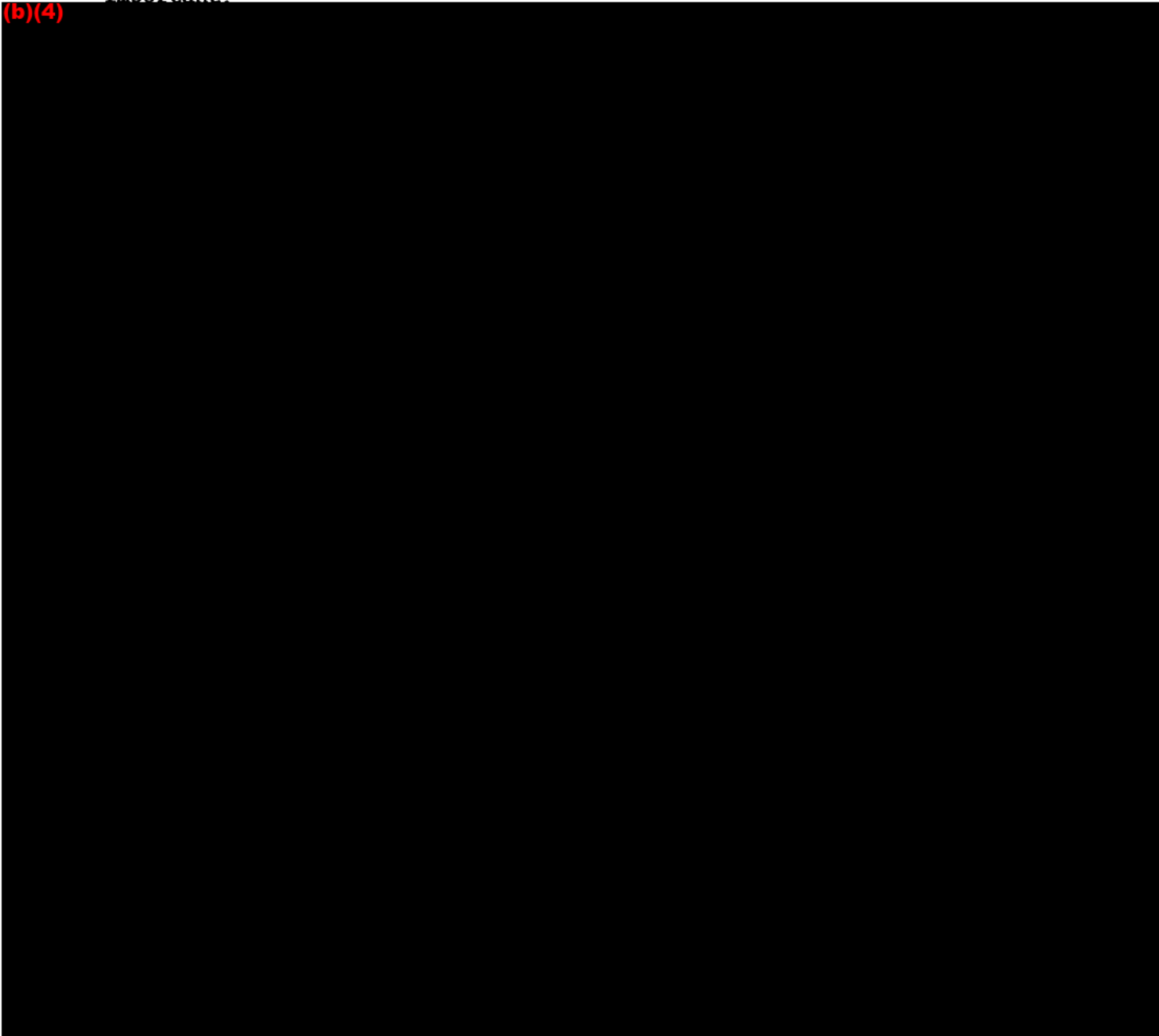
NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: Corneal Storage (until Keratoplasty)

(OPTISOL-GS : Chondroitin SO4 + Dexban + Streptomycin)
in 22 ml.

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

(b)(4)



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

1. EXPLAIN WHY NOT A DEVICE: _____

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

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

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

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS: _____

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

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

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

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

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED: _____

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

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 21, 1992

CHIRON INTRAOPTICS, INC.
ATTN: CAROL L. PATTERSON
9342 JERONIMO ROAD
IRVINE, CA 92718

510(k) Number: K924165
Received: 08-19-92
Product: OPTISOL-GS CORNEAL
STORAGE MEDIA

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

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 the Postmarket Surveillance Studies Branch at (301) 227-8639.

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

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

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

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

CHIRON



IntraOptics

K924/65

RECEIVED
19 AUG 92 11 28
FDA/CDRH/OCE/DIC

August 17, 1992

PMA DOCUMENT CENTER HFZ-401
Center for Devices & Radiological Health
Food & Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Re: 510(k) Notification: OPTISOL-GS Corneal Storage Media

To Whom It May Concern:

At this time, Chiron IntraOptics, Inc., is notifying the Administration that we wish to manufacture and market OPTISOL-GS Corneal Storage Media. OPTISOL-GS is a media used for storage of human donor cornea, after harvesting, until transplantation into a recipient.

Chiron currently holds approvals for 510(k)'s K894162 (OPTISOL Corneal Storage Media) and K883854 (DEXSOL Corneal Storage Media) which received substantial equivalence determinations on January 12, 1990 and November 16, 1988, respectively. The OPTISOL-GS media is almost identical to our OPTISOL media, the only difference is that the OPTISOL-GS media additionally contains 200 $\mu\text{g/mL}$ of streptomycin. This 510(k) includes information and test documentation which supports the addition of streptomycin (200 $\mu\text{g/mL}$) to the currently approved OPTISOL Corneal Storage Media. Streptomycin is an antimicrobial which is used in McCarey-Kaufman's M-K Corneal Storage Media which has been on the market prior to May 28, 1976.

Like our OPTISOL media, OPTISOL-GS media will also be used in conjunction with our currently approved and marketed OPTISOL Corneal Storage Media Container (K921729).

Included within this 510(k) notification are preclinical and clinical studies which were conducted in order to demonstrate the safety and effectiveness of OPTISOL-GS Corneal Storage Media (OPTISOL formulation (K894162) with 200 $\mu\text{g/mL}$ streptomycin).

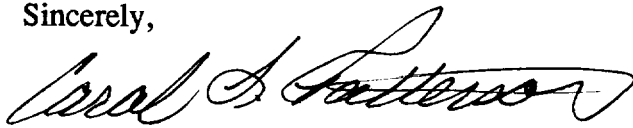
9342 Jeronimo Road
Irvine, CA 92718-1903
TEL: 714-768-4690
FAX: 714-768-4882

510(k) Notification: OPTISOL-GS Corneal Storage Media
August 17, 1992
Page 2 of 2

Chiron IntraOptics hopes that the information contained herein is found satisfactory to the FDA for review and approval.

If you have any questions or need clarification, please contact our office at (800) 553-3354, extension 327.

Sincerely,

A handwritten signature in cursive script, appearing to read "Carol L. Patterson".

Carol L. Patterson
Director, Regulatory Affairs/Quality Compliance

CLP/MS

attachments

Chiron IntraOptics, Inc
OPTISOL-GS Cornea
510(k) Supp

86-LYX
apparently
unclassified

A. Device Name:

Classification name: Synthetic Cell an

Common/usual name: Synthetic
Component.

Trade/proprietary name: OPTISOL-G.

How class I?

B. Establishment Registration Number:

Chiron IntraOptics, Inc.: 2027189

C. Device Classification:

The FDA has classified devices of this type as Class I
under paragraph 864.2220, CFR 21, "Synthetic Cell a
Components".

D. Performance Standard:

No performance standards have been established by the FDA to date for this device.

E. Draft Labeling:

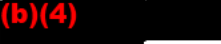
Draft labeling for OPTISOL-GS will be almost identical to that our currently marketed
OPTISOL product. The only difference is that labeling for OPTISOL-GS will identify
streptomycin as an ingredient. Please refer to Attachment 1 for copies of the OPTISOL
labeling and proposed OPTISOL-GS labeling.

13

F. Statement of Substantial Equivalence:

OPTISOL-GS Corneal Storage Media is substantially equivalent in both intended use and formulation to our currently marketed OPTISOL Corneal Storage Media (K894162). ✓
 Like our currently marketed OPTISOL Corneal Storage Media, OPTISOL-GS Corneal Storage Media is used for storage of donor cornea, after harvesting, until transplantation into a recipient. The OPTISOL-GS formulation is almost identical to our OPTISOL formulation, the only difference is that the OPTISOL-GS formulation additionally contains 200 µg/mL of streptomycin. Both OPTISOL and OPTISOL-GS contain gentamicin sulfate as an antimicrobial agent. The addition of streptomycin in OPTISOL-GS provides additional coverage against gentamicin-resistant bacteria. Streptomycin is an antimicrobial which is used in McCarey-Kaufman's M-K Corneal Storage Media which has been on the market prior to May 28, 1976. ✓ ←

(b)(4)

Our OPTISOL media is currently marketed with a two-year expiration date. The stability protocol used for OPTISOL-GS is almost identical to the stability protocol used for OPTISOL except for the testing related to streptomycin. Stability data has been generated on two lots of OPTISOL-GS for periods of time up to and (b)(4) 
 Analyses of these data have shown that streptomycin in the formulation has not adversely affected the stability profile. Based upon the data generated to date on OPTISOL-GS and historical data on OPTISOL, a one year expiration date has been assigned to OPTISOL-GS. This expiration date may be extended based upon results from future stability testing. ✓

The OPTISOL-GS is of comparable type and substantially equivalent to the following commercially available distributed corneal storage medias:

Chiron IntraOptics - 510(k) Approvals

Optisol Corneal Storage Media Container, Modified ✓
 K921729 - Approved June 9, 1992

Optisol Corneal Storage Media ✓
 K894162 - Approved January 12, 1990

Dexsol Corneal Storage Media Container, Modified
K921728 - Approved June 9, 1992

✓

Dexsol Corneal Storage Media
K883854 - Approved November 16, 1988

✓

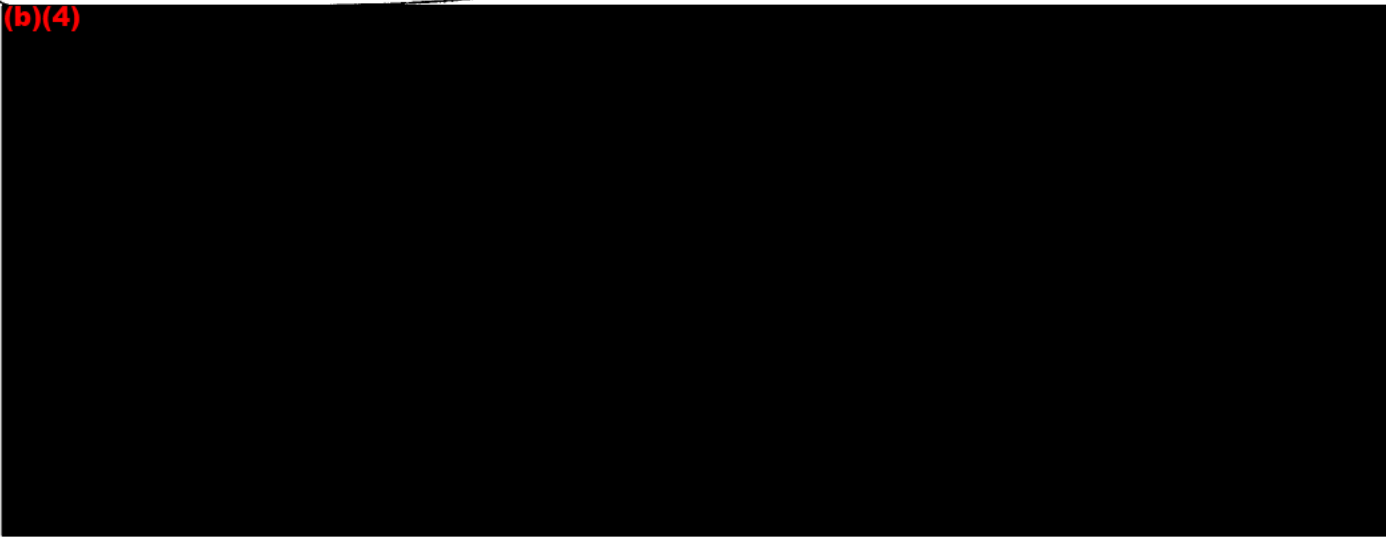
G. Summary of Safety and Effectiveness:

Please refer to Attachment 3 for the summary of safety and effectiveness.

✓

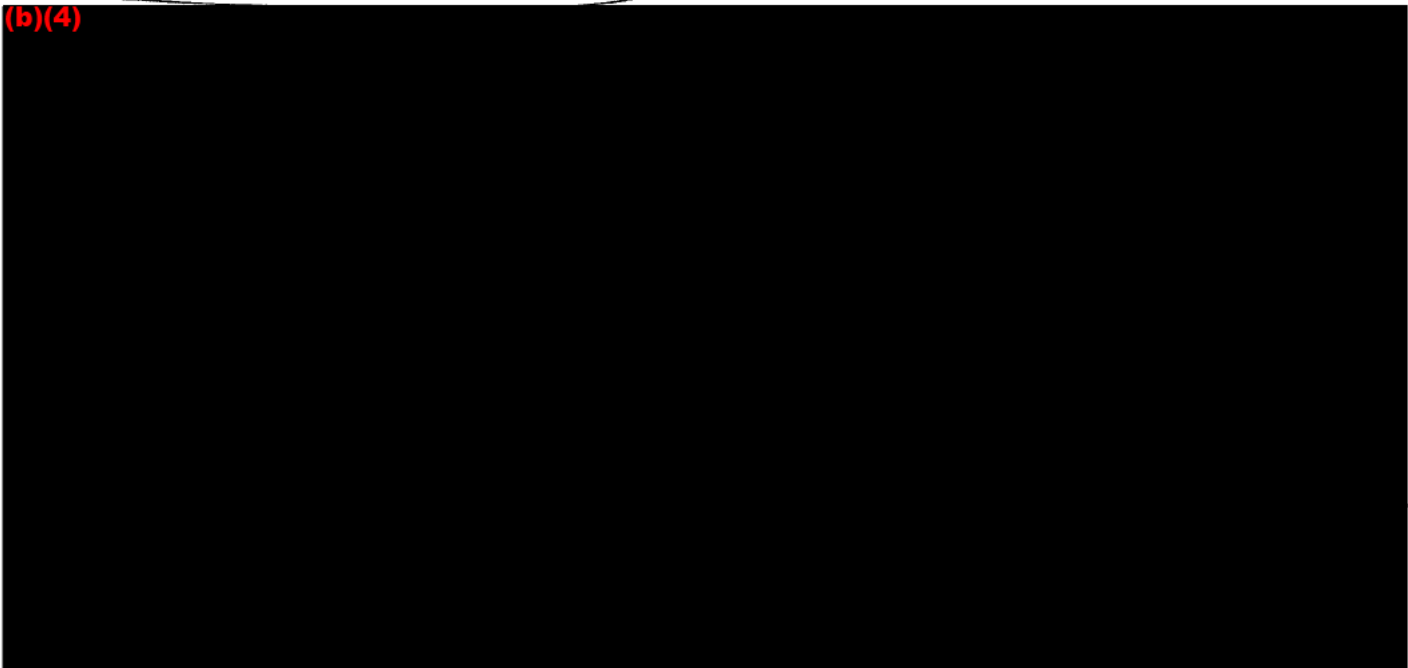
H. Preclinical Studies for OPTISOL-GS:

(b)(4)



I. Clinical Studies for OPTISOL-GS:

(b)(4)





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN - 9 1992

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Ms. Carol L. Patterson
Chiron Intraoptics
9342 Jeronimo Road
Irvine, California 92718

Re: K921728
Trade Name: Dexsol Corneal Storage Media
Container, Modified
Regulatory Product Class: I
Dated: March 23, 1992
Received: March 25, 1992

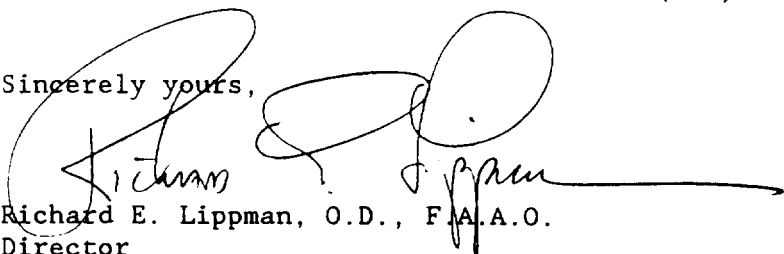
Dear Ms. Patterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, and 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. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a 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 on the labeling for your device, please contact the Division of Compliance Operations, Device Labeling Compliance Branch (HFZ-326) at (301) 427-1165. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,


Richard E. Lippman, O.D., F.A.A.O.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN - 9 1992

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Ms. Carol L. Patterson
Chiron Intraoptics
9342 Jeronimo Road
Irvine, California 92718

Re: K921729
Trade Name: Optisol Corneal Storage
Media Container, Modified
Regulatory Product Class: I
Dated: March 23, 1992
Received: March 25, 1992

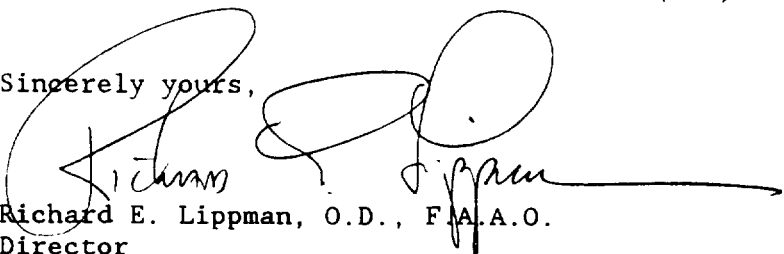
Dear Ms. Patterson:

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This letter immediately will allow you to begin marketing your device as described. 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 on the labeling for your device, please contact the Division of Compliance Operations, Device Labeling Compliance Branch (HFZ-326) at (301) 427-1165. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,


Richard E. Lippman, O.D., F.A.A.O.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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ATTACHMENT 1

Labeling for Currently Marketed OPTISOL Corneal Storage Media
and
Proposed Draft Labeling for OPTISOL-GS Corneal Storage Media

000001

Labeling for Chiron's currently marketed OPTISOL Corneal Storage Media immediately follows this page.

Optisol^R

current

Chondroitin Sulfate/Dextran Corneal Storage Medium

Description

OPTISOL is a sterile, buffered tissue culture medium which is enhanced with polypeptides, an osmotic agent (dextran), chondroitin sulfate, gentamycin sulfate and phenol red indicator.

Indications

OPTISOL is a biocompatible, enhanced tissue culture media for storage of human corneas suitable for keratoplasty for up to 14 days under refrigeration (2° - 8°C).

Precautions

Sterile technique should be used throughout the keratoplasty procedure.

Each container of medium should be visually inspected for color prior to use. The medium should be a light rosy-orange color. A change of color from rosy-orange to yellow indicates a pH shift, possibly due to bacterial contamination. A color change from rosy-orange to red also indicates an unacceptable pH shift. Do not use solution that appears cloudy. In the event of such change, return the unopened container to the manufacturer for evaluation and replacement.

Instructions for Use

Label the container with a description of the cornea. Break the seal on container cap. Proceed as follows.

Aseptic Conditions:

1. Loosen cap of container.
2. Lift off cap and place adjacent to sterile field with inner cap face up.

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000003

3. Aseptically transfer cornea. Carefully place the corneal button on pedestal of container with endothelium up. To avoid floating the cornea, break surface of storage medium with edge of cornea.
4. Replace and tighten container cap. To assure seal integrity, avoid spilling the media into the thread area of the container cap.
5. Store cornea with endothelium up.

In Situ:

1. Loosen container cap to top thread. Do not remove cap until immediately before transfer of the cornea to the storage medium.
2. Remove cap with a sterile forcep. Remove the forcep from sterile field. Transfer the cornea to the storage medium as described in steps #3, 4, & 5 above.

Storage

OPTISOL should be stored between 2^o and 8^oC until ready for use. DO NOT FREEZE.

Caution

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

How Supplied

OPTISOL is available in 22 ml containers packaged in boxes of 6. The container is single use only, do not re-use.

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Proposed Draft Labeling for Chiron's OPTISOL-GS Corneal Storage Media immediately follows this page.

000005 *26*

OPTISOL-GS K

**Chondroitin Sulfate/Dextran
Corneal Storage Media**

Description ✓

OPTISOL-GS is a sterile buffered tissue culture medium which is enhanced with polypeptides, an osmotic agent (dextran), chondroitin sulfate, gentamicin sulfate, streptomycin and phenol red indicator.

Indications ✓

OPTISOL-GS is a biocompatible, enhanced tissue culture media for storage of human corneas suitable for keratoplasty for up to 14 days under refrigeration (2°-8°C).

Precautions ✓

Sterile technique should be used throughout the keratoplasty procedure.

Each container of medium should be visually inspected for color prior to use. The medium should be a light rosy-orange color. A change of color from rosy-orange to yellow indicates a pH shift, possibly due to bacterial contamination. A color change from rosy-orange to red also indicates an unacceptable pH shift. Do not use solution that appears cloudy. In the event of such change, return the unopened container to the manufacturer for evaluation and replacement.

Instructions for Use

Label the container with a description of the cornea. Break the seal on container cap. Proceed as follows.

Aseptic Conditions:

1. Loosen cap of container.
2. Lift off cap and place adjacent to sterile field with inner cap face up.
3. Aseptically transfer cornea. Carefully place the corneal button on pedestal of container with endothelium up. To avoid floating the cornea, break surface of storage medium with edge of cornea.
4. Replace and tighten container cap. To assure seal integrity, avoid spilling the media into the thread area of the container cap.
5. Store cornea with endothelium up.

In Situ:

1. Loosen container cap to top thread. Do not remove cap until immediately before transfer of the cornea to the storage medium.
2. Remove cap with a sterile forcep. Remove the forcep from sterile field. Transfer the cornea to the storage medium as described in steps #3, 4, and 5 above.

000006 27

Storage

OPTISOL-GS should be stored between 2° and 8°C until ready for use. DO NOT FREEZE.

CAUTION

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

How Supplied

OPTISOL-GS is available in 22 mL containers packaged in boxes of 6. The container is single use only, do not re-use.

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ATTACHMENT 2

Advances in Corneal Preservation

by

Richard L. Lindstrom, MD

000008

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ATTACHMENT 3

Summary of Safety and Effectiveness

24

000103

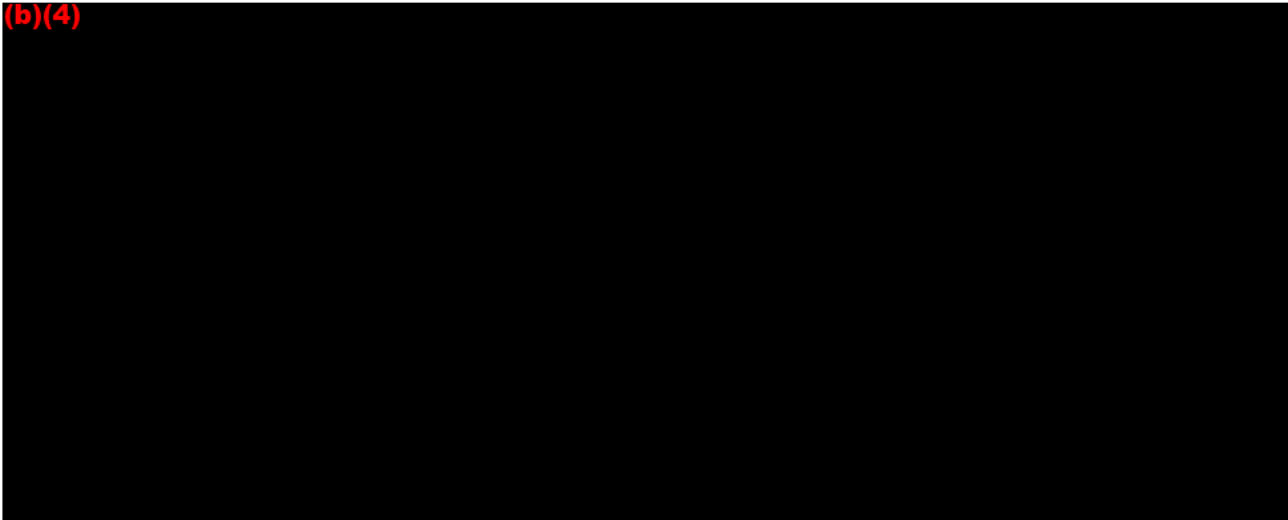
Summary of Safety and Effectiveness

Description

OPTISOL-GS Corneal Storage Media is substantially equivalent in both intended use and formulation to our currently marketed OPTISOL Corneal Storage Media (K894162). Like our currently marketed OPTISOL Corneal Storage Media, OPTISOL-GS Corneal Storage Media is used for storage of donor cornea, after harvesting, until transplantation into a recipient. The OPTISOL-GS formulation is almost identical to our OPTISOL formulation, the only difference is that the OPTISOL-GS formulation additionally contains 200 µg/mL of streptomycin. Both OPTISOL and OPTISOL-GS contain gentamicin sulfate as an antimicrobial agent. The addition of streptomycin in OPTISOL-GS provides additional coverage against gentamicin-resistant bacteria.

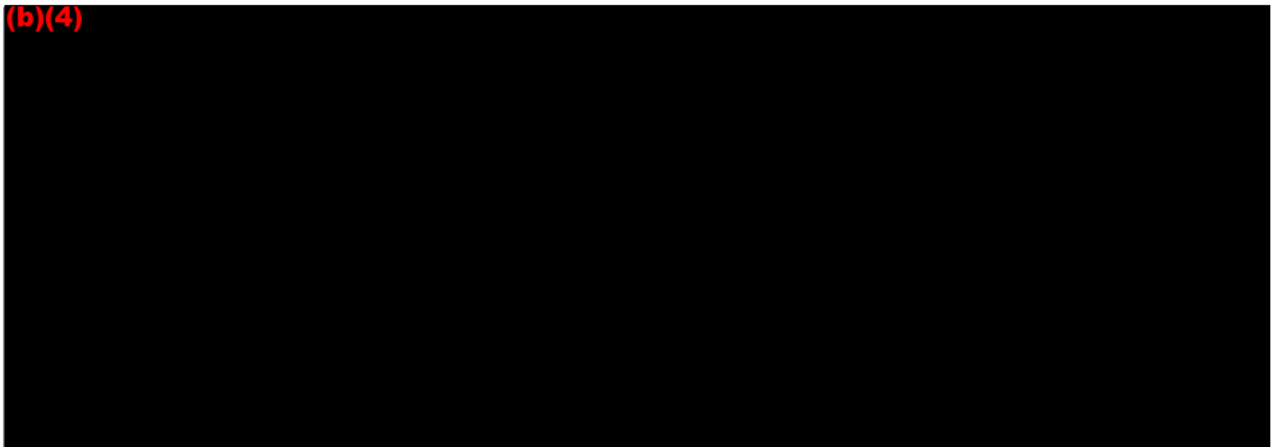
Manufacturing/Stability

(b)(4)



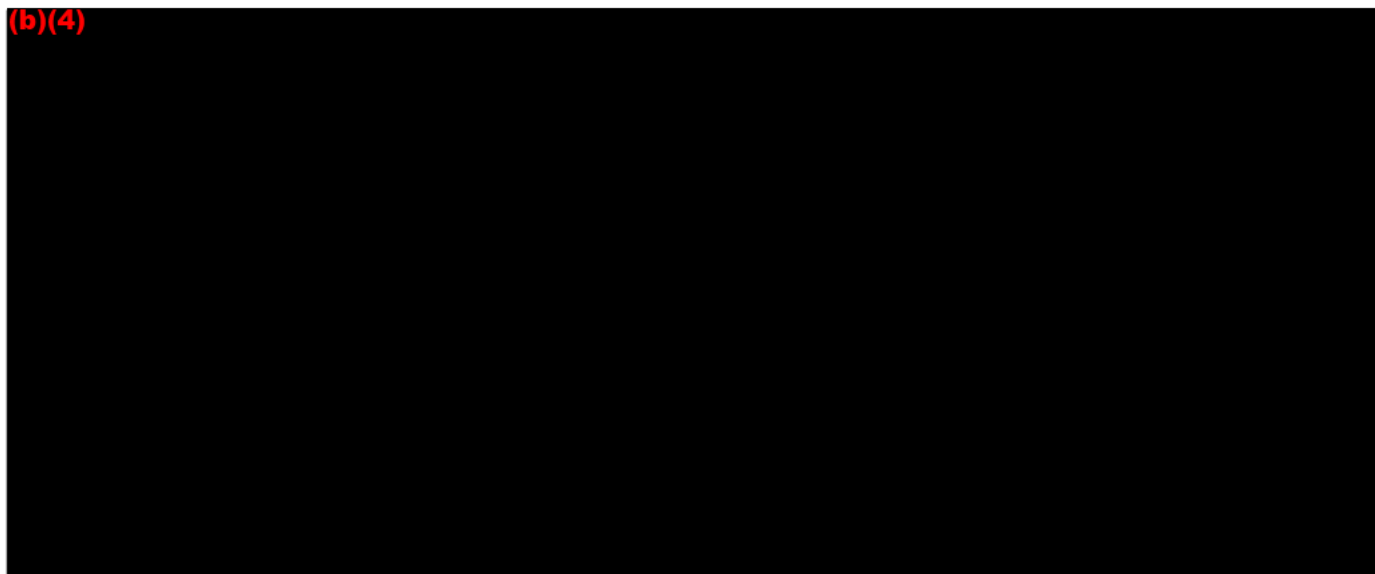
Preclinical Studies

(b)(4)



Clinical Studies

(b)(4)



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000105

ATTACHMENT 4

Preclinical Studies

000106

130

Preclinical Studies

(b)(4)



000107

21

Subject: Final Report

Date: December 2, 1991

Protocol #: 91-07-01-436

Experiment Title: Effectiveness of the Combination of Streptomycin and Gentamicin Sulfate as an Antimicrobial Agent for Optisol

**Personnel &
Responsibilities:**

Study Director

Study Investigator

Quality Assurance Unit

Sponsor

Study Date

Location

Approvals:

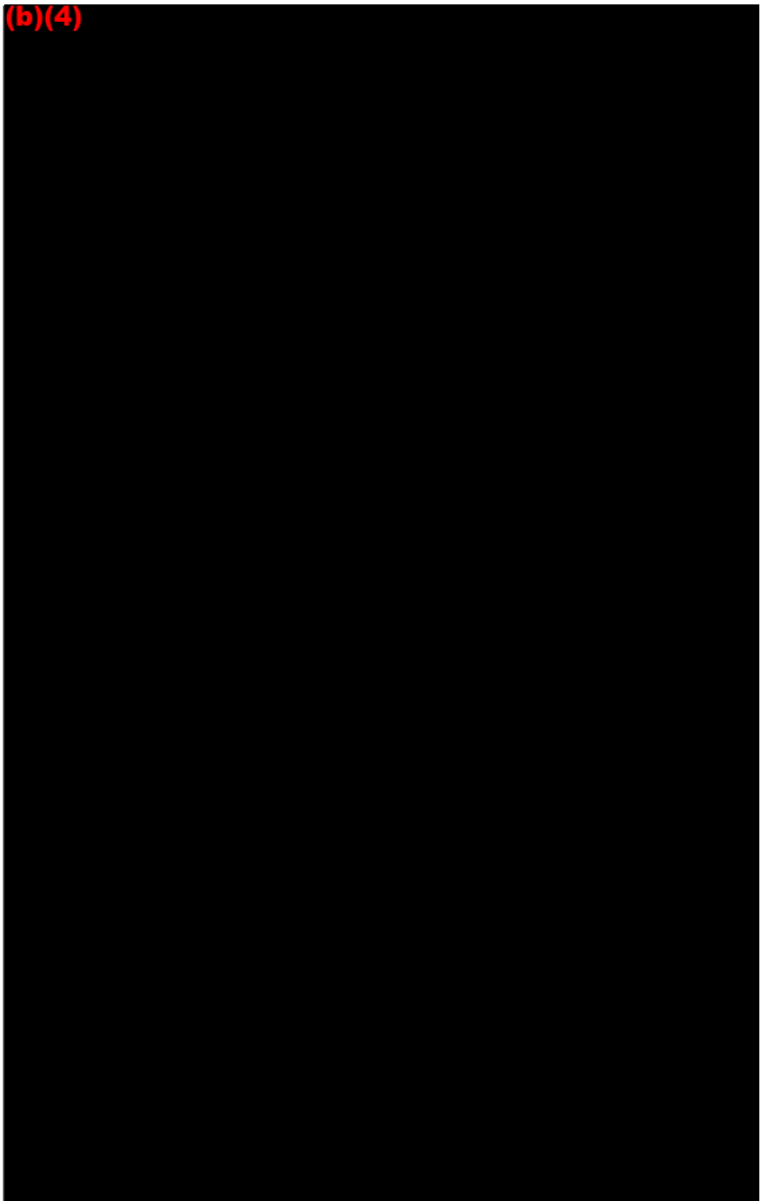
Study Director

Study Investigators

Quality Assurance Unit

Sponsor

(b)(4)

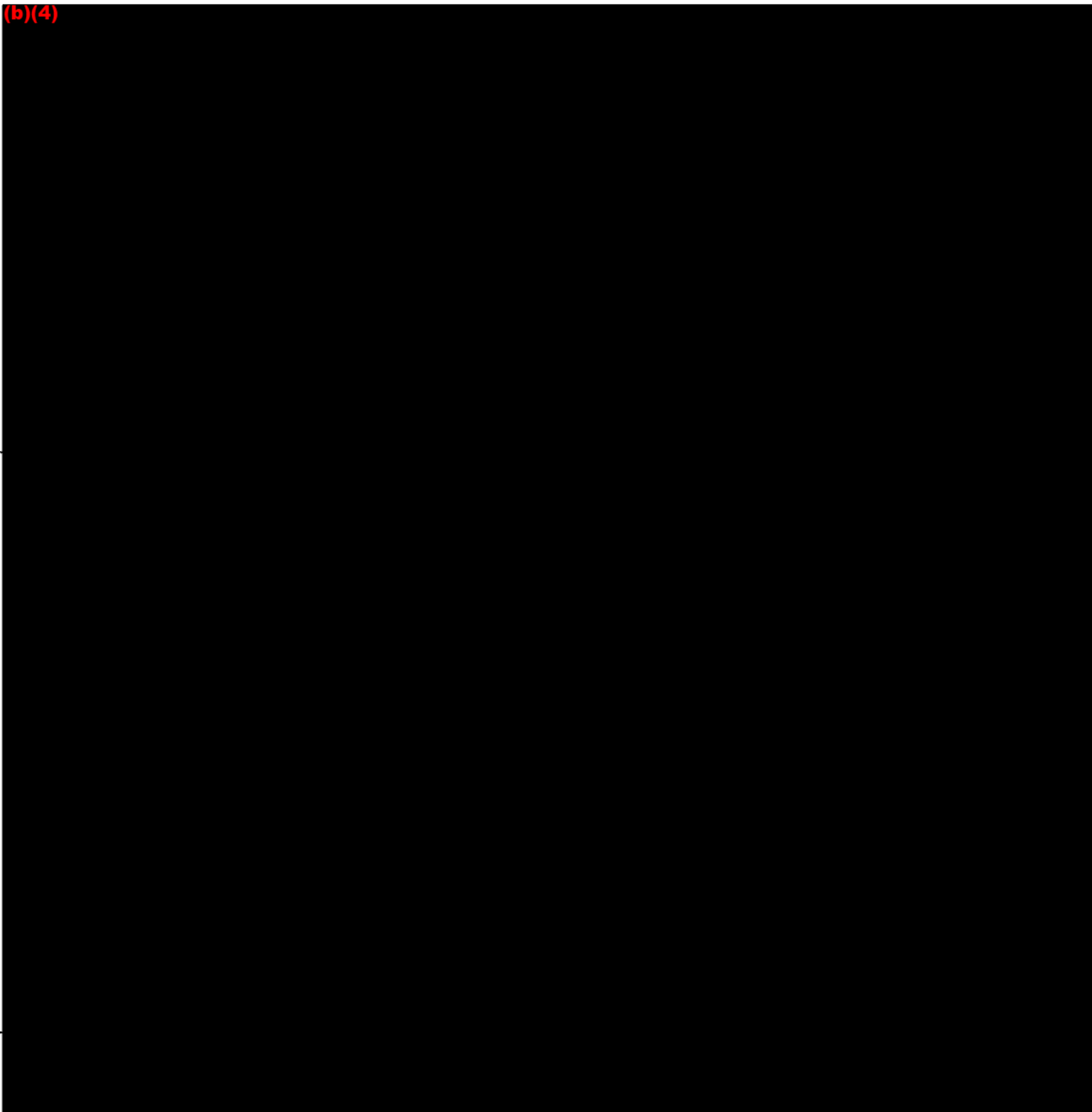


000108

OBJECTIVE

The objective of this study is to evaluate the effectiveness of Streptomycin and Gentamicin Sulfate as an antimicrobial preservative for Optisol.

MATERIALS



ATTACHMENT 5

Clinical Studies

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ATTACHMENT 6

Adverse Safety & Effectiveness Information

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000204

Chiron IntraOptics
OPTISOL-GS Corneal Storage Media
510(k) Application

**Certification and Summary of Adverse Safety and Effectiveness
Information Pursuant to 513(f) of the Federal Food,
Drug and Cosmetic Act**

I certify, to the best of my knowledge, that a reasonable search of all information known or otherwise presently available to Chiron IntraOptics has been conducted. Such search is defined as examining BRS/*Medline*, relevant to company documents, patents, etc. concerning the safety and effectiveness information for the Corneal Storage Media. No adverse safety and effectiveness data relating to this media were discovered in the search. Attached to this certification is a summary of and citation to the adverse safety and effectiveness data found in that search*.

*Pursuant to Section 513(f) of the Federal Food, Drug, and Cosmetic Act, information submitted to the Secretary under MDR, Section 519 of the Federal Food, Drug, and Cosmetic Act, has not been included.



Carol L. Patterson
Director, RA/QC
Chiron IntraOptics
9342 Jeronimo Road
Irvine, CA 92718
(714) 768-4690

August 17, 1992

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