JUN - 1 2001

K010315

510(k) Summary

[As required by 21 C.F.R. § 807.92 (c)]

January 31, 2001

Submitter's Name: iScreen, LLC
668 Colonial Road, Suite 1
Memphis, Tennessee 38117
Phone: (901) 888-0071
Fax: (901) 888-0072

Contact Person: Peter Thrall, Chief Operating Officer

Device Trade Name: iScreen Vision Screener

Common Name: Ophthalmic Refractometer/Ophthalmic Camera

Classification Regulations:
Ophthalmic Refractometer – 21 C.F. R. § 886.1760
Ophthalmic Camera – 21 C.F. R. § 886.1120

Legally Marketed Device to Which Equivalence is Claimed:

- MTI Photoscreener (K934880)
- Digital Retinoscopic Photometer (K951179)

Description of the Device:

The iScreen Vision Screener belongs to a generic class of ophthalmic devices that utilize the technique of eccentric photorefraction to record the retinal reflex and ocular status of the eye. All of these instruments have similar primary components: 1) an illumination source, and 2) a recording device. These instruments project a beam of light onto the face and eyes of a patient. The recording device, typically a digital or film-based camera, records an image of the retinal reflex, sometimes called the "red reflex." The retinal reflex provides indications of the ability of the eye to focus light. The ocular status is also recorded in the same image

since any degradation of the optics of the eye that would affect vision will also degrade the beam of light generated by the illumination source.

Similarly, the iScreen Vision Screener system is composed of two parts: 1) a camera unit that records the retinal reflex and ocular status, and 2) a computer that stores the data for later interpretation. The camera unit and computer are powered by a transformer that plugs into a standard 110 VAC wall outlet. The camera unit is supplied with 12 VDC and the computer with 14 VDC. The camera unit is similar to any ophthalmic camera, being comprised of a housing for components, a digital camera for recording the retinal reflex and ocular status, a flash system for generating light, a fixation device for attracting the patient's attention and an alignment camera that helps the user position the patient very accurately. The digital camera is becoming widely used in nearly all aspects of medical imaging. The light source used in this device is a standard photographic flash that is fitted with an attenuator that shapes the beam in to a line of light. The attenuating mask is a small aluminum plate with a 3 mm X 10 mm slot, restricting the output area to roughly 5% of the original. The intensity of light is attenuated to 2.04×10^{-6} W/cm^2, which is much less than standard off-the-shelf photoflash equipment.

Summary of Intended Use:

The iScreen Vision Screener is a tool for screening vision problems in humans. It records and measures the retinal reflex and ocular status, providing data points for analysis and interpretation.

Summary of Technological Characteristics of the iScreen Vision Screener as Compared to the Predicate Devices:

The iScreen Vision Screener is very similar in function and purpose to the MTI Photoscreener (K934880), Digital Retinoscopic Photometer (K951179), and Ophthalmic Refractometer/camera devices. All of these devices use an illumination source and camera to record and measure the retinal reflex and ocular status. The MTI Photoscreener and Digital Retinoscopic Photometer record grayscale images, while the iScreen Vision Screener records a color (24 bit) image. The Digital Retinoscopic Photometer and the iScreen Vision Screener record images with a digital camera, which are subsequently transferred to a computer. The MTI Photoscreener is a film-based system, using a Polaroid™ camera to record information. Both the MTI Photoscreener and iScreen Vision Screener rely on human interpretation of the results of the photoscreening image, whereas the Digital Retinoscopic Photometer uses computer algorithms to measure image parameters.

Both The MTI Photoscreener and iScreen Vision Screener employ a fixation component made up of blinking light emitting diodes (LED's) and an audible sound to attract the patient's attention so that they fixate very close to the camera. The iScreen Vision Screener also uses an infrared camera to assist the user in positioning the patient in a dimly lit room. The use of an infrared camera for patient positioning is not significantly different, and does not affect the primary purpose or function of the device.

The Digital Retinoscopic Photometer and iScreen Vision Screener both use 110VAC as a power source. However, the iScreen Vision Screener employs an in-line transformer so that only 12VDC is supplied to the camera unit and 14VDC to the computer. The MTI Photoscreener is a battery-powered unit.

All eccentric photorefractors are marketed for similar purposes. Since a system employing this technique does not require verbal response from the patient, it can be used to screen patients of all ages for vision problems, and becomes particularly useful for preverbal children.

Safety and Effectiveness Statement

To assure that the device is safe and effective, all finished devices are tested and must meet all required release specifications before distribution. The testing required for release includes, but is not limited to the following:

- Camera
    1. Printed Circuit board
        a. Power distribution to electronic components
        b. Fixation LED's
    2. Wiring harness
    3. Photoflash
        a. Charging circuitry
        b. Intensity
        c. Alignment
    4. Digital camera
        a. Focus
        b. Aperture
        c. Alignment
    5. IR camera
        a. Focus
        b. Alignment
    6. Image quality

7. Mechanical integrity

- Computer
  8. Cabling
  9. Communications with camera device
  10. Software functionality

The required testing is defined by written and approved procedures that conform to the device design specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2001

Mr. Peter Thrall
Chief Operating Officer
iScreen™, LLC
668 Colonial Road, Suite 1
Memphis, TN 38117

Re: K010315
Trade Name: iScreen Vision Screener
Regulatory Class: II
Product Code: HKI
Regulation: 886.1120
Dated: May 1, 2001
Received: May 7, 2001

Dear Mr. Thrall:

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 (for the indications for use stated in the enclosure) 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K010315

Device Name: iScreen Vision Screener

Indications For Use:

The iScreen Vision Screener is a tool for screening vision problems in humans. It records and measures the retinal reflex and ocular status, providing data points for analysis and interpretation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K010315

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Chief Operating Officer
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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
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510(k) Number (if known): K010315

Device Name: iScreen Vision Screener

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K010315

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Jan Calloway

Subject: 510(k) Number K 010315 / S1

To: The Record - It is my recommendation that the subject 510(k) Notification: SE

☐ Refused to accept.
☐ Requires additional information (other than refuse to accept).
☒ Is substantially equivalent to marketed devices.
☐ NOT substantially equivalent to marketed devices.
De Novo Classification Candidate? ☐ YES ☐ NO
☐ 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
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ 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 indication for use form (required for originals received 1-1-96 and after)
Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

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

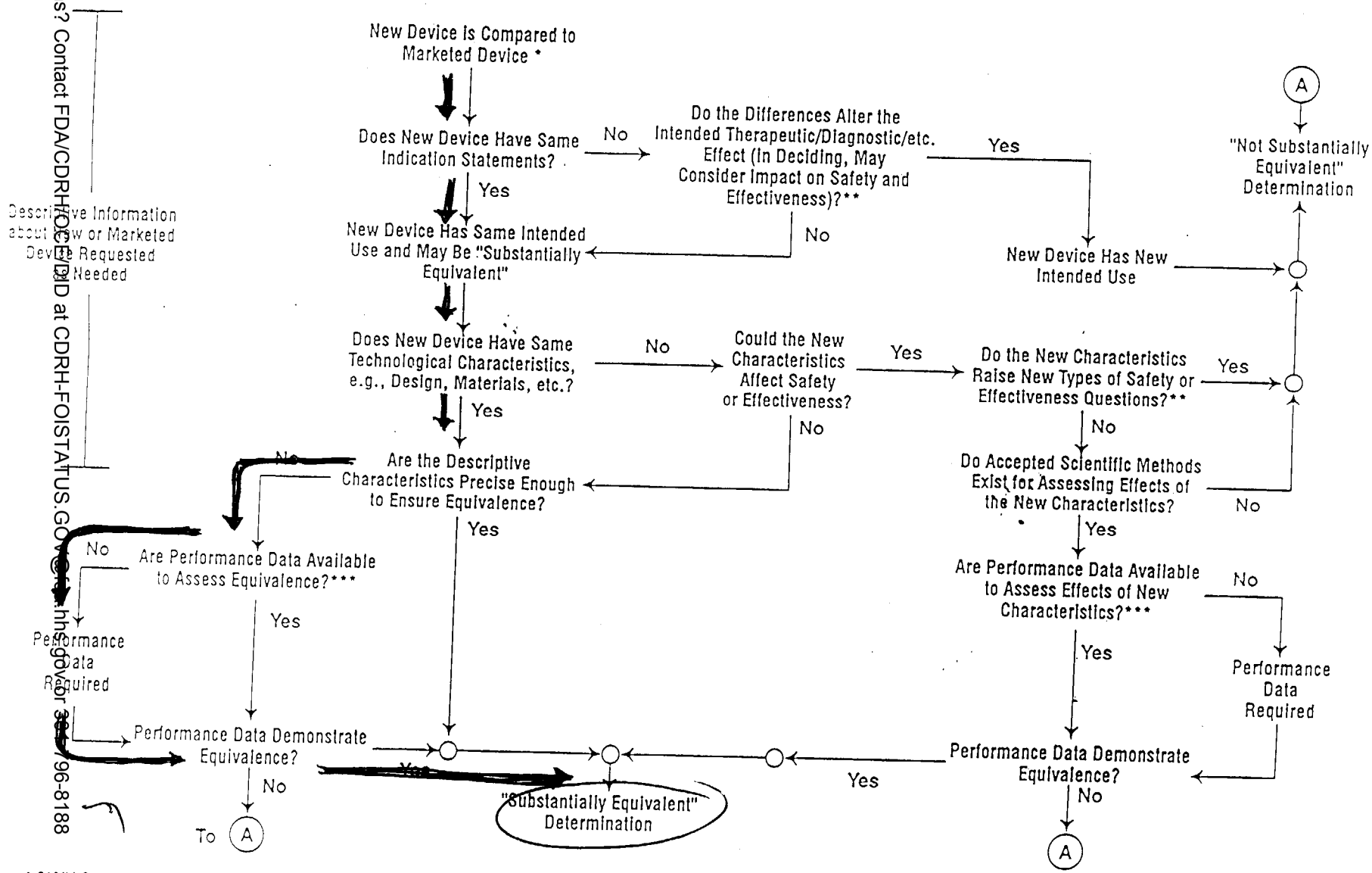
HKI 886.1120 Class II

Review: Kenneth Beam (Branch Chief) DSPB (Branch Code) 5/30/01 (Date)

Final Review: David A. Whipple for DOED (Division Director) 5/31/01 (Date)

Revised 8/17/99

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 Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Technical Information is Sometimes Required.

*** Data May Be Found in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 010315

Reviewer: Jan C. Calloway

Division/Branch: DOED/DSDB

Device Name: iScreen Vision Screener

Product To Which Compared (510(K) Number If Known): K934880 and K951179

	YES	NO	
1. Is Product A Device	✓		If **NO** = Stop
2. Is 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?	✓		Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use: The iScreen Vision Screener is a tool for screening vision problems in humans. It records and measures the retinal reflex and ocular status, providing data points for analysis and interpretation.

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. 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.

- The device is not life-supporting or sustaining, is not an implant or a kit, and does not contain a drug or biological product as a component. It is a prescription device.

- The iScreen system is made up of the screening unit, portable computer running Microsoft Windows 98, and interconnect cables. The iScreen software provides an easy interface for the user to enter patient information, and controls the digital and analog cameras in the screening device itself. The flash, fixation LED's and IR LED's are not software controlled, but are controlled by switching hardware. This design maximizes safety since all illumination sources are switched by the user or by hardware components and the software is used for data acquisition and storage. The photoflash is triggered by the CMOS camera using a standard low-voltage TTL circuit. IR LED's are switched by the IR camera power supply, and the fixation LED's are switched on by the user. The iScreen software does not allow users access to any other features or functions of the computer or operating system. When the user turns the computer on, the iScreen control software is launched. When the user exits the iScreen program, the software shuts down the computer. This increases reliability, eliminating potential problems or conflicts from unintended use of the computer.

  The iScreen program has 3 core modules:
  - Image Acquisition
  - Transmit Images
  - Analysis Results

- No part of the device is supplied sterile. The only component surface that comes in contact with the patient is the headrest. This component is curved to minimize the risk or injury. The headrest is made from molded unvulcanized rubber. This material does not present any significant biocompatibility issues.

- The iScreen Vision Screener belongs to a generic class of ophthalmic devices that utilize the techniques of eccentric photorefraction to record the retinal reflex and ocular status of the eye relying on human interpretation of data to determine the results of a screening.

  The iScreen Vision Screener is composed of two parts: 1) a camera system that records the retinal reflex and ocular status, and 2) a computer that stores the data for later interpretation.

This device in minimally invasive. A standard photographic flash is used to illuminate the face and eyes. The infrared (IR) camera uses light emitting diodes (LED's) to illuminate the patient with IR light in a dimly lit room.

The iScreen Vision Screener uses a 110VAC as a power source and employs an in-line transformer so that only 12VDC is supplied to the camera unit and 14VDC to the computer.

(b) (4)

[redacted]

Telephone hold on March 16, 2001: I sent a list of questions addressed to Mr. Peter Thrall by facsimile (attached) on March 15, 2001. I spoke with Ms. Alison Sykes on that day telling her that this action puts their document on telephone hold until they respond to the questions. Mr. Peter Thrall was not in, so she would give the facsimile to Mr. Jack Bellows.

RECOMMENDATION: This reviewer recommends that this document be placed on **telephone hold** until the applicant has officially responded to the questions sent to him by facsimile on March 15, 2001.

REVIEW ADDENDUM - May 21, 2001

A supplement answering the deficiencies faxed to the company on March 15, 2001 was received on May 7, 2001.

1. *For comparing the ocular safety of one pulsed light source to another to determine if there is any phototoxicity hazard, it is necessary to compare the "effective retinal thermal radiant exposure" produced by the light sources. Thus, the irradiance data of the light sources for the device and a predicate provided in the submission is not sufficient to document the relative safety of the device.*

   Please provide a comparison of the "effective retinal thermal radiant exposure" for the device with a predicate device (see reference below). Alternatively, it may be possible to demonstrate equivalence for pulsed white light sources with similar spectral emissions by showing equivalence of the following parameters for the device and a predicate. The parameters include pulse width, spectral emissions, integrated radiant exitance (joules/cm2) or integrated radiant intensity (joules/Sr), and the area illuminated on the retina.

   Note: The weighting function for determining effective retinal thermal radiant exposure may be found in:

   "2000 Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, American Conference of Governmental Industrial Hygienists,

(ACGIH, Cincinnati, OH, 1996)". A copy of the booklet may be obtained for a fee from ACGIH. Telephone Number (513) 742-2020

Response: Information regarding the photoflash was submitted along with the statement that the low level of light intensity from the photoflash is apparent and causes no risk to the patient or user. The manufacturer of the predicate device provided similar information to establish the ocular safety of the flash unit in Appendix 5 of K951179.

Comment: The response regarding phototoxicity was reviewed by Dr. Robert Landry, OST and found to be acceptable.

2. *In your Instruction Manual, mention is made of transmitting images to a reading center. Please provide the following information regarding this aspect of the device:*

   a) *Please provide a description of the method of communication with the reading centers. For instance, are these images sent by phone, wireless, Internet, etc.?*

   b) *How is the "results information" returned to the referring physician?*

   c) *Please describe any digitization schemes.*

   d) *Please describe imaging (if appropriate) such as use of DICOM or JPEG standards.*

   e) *Is any diagnostic software employed at the reading centers? If so, please refer to FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 29, 1998): www.fda.gov/cdrh/ode/software.pdf and "Off-The-Shelf Software Use in Medical Devices" (September 9, 1999): http://www.fda.gov/cdrh/ode/otssguid.pdf*

Response: The specific responses to the questions regarding telemedicine can be found on page 2 of the submission.

Comment: The response regarding telemedicine was reviewed by Dr. Everette Beers, DSDB Engineer, and found to be acceptable.

3. *The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires security of patient's records. Please describe security measures and certify conformance to some type of data security.*

Response: The specific response to this question may be found on page 3 of the submission.

Comment: The response regarding security of patient records was reviewed by Dr. Everette Beers, DSDB Engineer, and found to be acceptable.

4. *You must demonstrate electrical safety with bench testing, or declare conformance to an electrical safety standard recognized by FDA (e.g., International Electrotechnical Committee (IEC) 60601-1), or certify compliance with other electrical safety standards (e.g. Underwriters Laboratory (UL) 544, UL 2601-1, etc.; testing data may be required).*

   Response: iScreen certifies that the Digital Vision Screener will meet the standard set forth in IEC 60601-1 prior to iScreen's marketing of the device.

   Comment: Acceptable.

5. *You have submitted documentation of your software functional test plan and validation, verification and testing. Please also submit the version number and date of your software and the pass/fail criteria. Please state whether your device complies with either the May, 1998 ODE Software Guidance, "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices" or IEC 60601-1-4.*

   Response: The responses regarding software are found on pages 3 and 4 and Amendment 1 of the submission.

   Comment: The response regarding software was reviewed by Ms. Quynh Hoang, DSDB Engineer, and found to be acceptable.

6. *Please add the following prescription device caution to your labeling:*

   "Caution: Federal law restricts this device to sale by or on the order of a Physician or Practitioner" (CFR 801.109(b)(1))."

   Response: The Prescription Device Caution statement has been added to the device labeling.

   Comment: Acceptable.

7. *Labeling for Phototoxicity. Please add the following to your labeling (per ISO 10942):*

   "WARNING: Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. This device should be used with filters that eliminate UV radiation (<400 nm) and, whenever possible, filters that eliminate short-wavelength blue light (<420 nm). The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

   Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument

or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography."

Response: The Phototoxicity Warning label has been added to the device labeling.

Comment: Acceptable.

RECOMMENDATION: This device should be considered substantially equivalent to the predicate device.

Jan C. Callaway

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

1. Explain why not a device: N/A

2. Explain why not subject to 510(k): N/A

3. How does the new indication differ from the predicate device's indication: N/A

4. Explain why there is or is not a new effect or safety or effectiveness issue: N/A

5. Describe the new technological characteristics: N/A

6. Explain how new characteristics could or could not affect safety or effectiveness: N/A

7. Explain how descriptive characteristics are not precise enough: N/A

8. Explain new types of safety or effectiveness questions raised or why the questions are not new: N/A

9. Explain why existing scientific methods can not be used: N/A

10. Explain what performance data is needed: N/A

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: N/A

ATTACH ADDITIONAL SUPPORTING INFORMATION

(b) (4)

(b)(4)

[redacted]

(b) (4)

(b) (4)

(b) (4)

(b) (4)

[redacted]

18

(b) (4)

(b) (4)

(b) (4)

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(b) (4)

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

May 07, 2001

ISCREEN, LLC
668 COLONIAL RD. (SUITE 1)
MEMPHIS, TN 38117
ATTN: PETER THRALL

510(k) Number: K010315
Product: ISCREEN VISION SCREENER

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

iScreen™
gital Vision Screening Technology

iScreen™ LLC
668 Colonial Road, Suite 1
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901-888-0071
Fax 901-888-0072
Toll free 888-873-6711
info@iscreenllc.com

May 1, 2001

Jan C. Callaway
Scientific Reviewer (DOD/DSDB)
Department of Health and Human Services
Public Health Service
Food and Drug Administration

RE: Additional information for K010315
iScreen™ Vision Screener, iScreen™, LLC

Dear Ms. Callaway,

Thank you for your continued assistance throughout the process of revising our 510(k) submission. Please find below, our responses to requests for additional information corresponding to the numbered items in the FDA memorandum document of March 15, 2001. Additional image information is given in item 2c, and revised Software Pass/Fail criteria (related to item 5b) are provided in an attachment.

1) *Please provide a comparison of the "effective retinal thermal radiant exposure" for the device with a predicate device. Alternatively, it may be possible to demonstrate equivalence for pulsed white light sources with similar spectral emissions by showing equivalence of the following parameters for the device and predicate. The parameters include pulse width, spectral emissions, integrated radiant exitance (joules/cm^2) or integrated radiant intensity (joules/Sr), and the area illuminated on the retina.*

   We at iScreen realize the tremendous importance of ensuring safety for persons that use the device. Perhaps the most significant feature of any photoscreening system is the photoflash since it is the only invasive quality of the device. We can show that the iScreen™ Digital Vision Screener has a photoflash intensity that is much less than a typical family photographic flash units. Consider, for example, the following characteristics of the iScreen™ Digital Vision Screener:

(b) (4) [redacted]

(b) (4) [redacted]

   We believe that the low level of light intensity from the photoflash is apparent and causes no risk to the patient or user. We note that the manufacturer of the predicate device provided similar information to establish the ocular safety of the flash unit in Appendix 5 of 510(k) number K951179. Therefore, in light of the low flash intensity of

the iScreen™ device flash, we question the need for additional safety data.

2) *In your instruction Manual, mention is made of transmitting images to a reading center. Please provide the following information regarding this aspect of the device.*

a) *Please provide a description of the method of communication with the reading centers. For instance, are these images sent by phone, wireless, Internet, etc.?*

(b) (4) [redacted]

b) *How is the "results information" returned to the referring physician?*

Images are viewed by a trained technician and the results of the interpretation are conveyed to the screening location via computer-generated facsimile. At no time during the communication, interpretation or reporting process are images altered or annotated.

c) *Please describe any digitization schemes.*

(b) (4) [redacted]

Additional Image Information:

(b) (4) [redacted]

d) *Please describe imaging (if appropriate) such as use of DICOM or JPEG standards.*

(b) (4) [redacted]

e) *Is any diagnostic software employed at the reading centers? If so, please refer to FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 29, 1998): www.fda.gov/cdrh/ode/software.pdf and "Off-The-Shelf Software Use in Medical Devices" (September 9, 1999): http://www.fda.gov/cdrh/ode/otssguid.pdf.*

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No diagnostic software is employed in any part of the process. Technicians can view images in any software package with standard JPEG image viewing capabilities.

3) *The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires security of patient's records. Please describe security measures and certify conformance to some type of data security.*

While it is our understanding that the HIPAA privacy regulations may be extended beyond the April 14, 2001 implementation date for further consideration, patient confidentiality is of paramount concern to iScreen™. At this time, security of patient records is guaranteed by password protection of the database. Only qualified personnel have access to records that have patient information coupled to results of image interpretation. At the time of screening (prior to image interpretation), generic patient information can be entered on a voluntary basis. Data fields are provided for patient name, ID, and/or age. However, this data is not necessary for image acquisition. Once the image has been evaluated by a qualified technician, a report containing patient name and ID along with results of image interpretation is automatically sent to the originating screening location by computer-generated facsimile. Image interpretation results are stored in the database at this time. JPEG image files are not identified by any patient information, but are numbered sequentially, with each image being uniquely identified by a vision screener ID number and a concatenated incremental value. Image files are therefore unique regardless of where the image was created (screening location).

4) *You must demonstrate electrical safety with bench testing, or declare conformance to an electrical safety standard recognized by FDA (e.g., International Electrotechnical Committee (IEC) 60601-1), or certify compliance with other electrical safety standards (e.g. Underwriters Laboratory (UL) 544, UL 2601-1, etc.; testing data may be required).*

iScreen certifies that the Digital Vision Screener will meet the standard set forth in IEC 60601-1 prior to iScreen's marketing of the device.

5) *You have submitted documentation of your software functional test plan and validation, verification and testing. Please also submit the version number and date of your software and the pass/fail criteria. Please state whether your device complies with either the May 1998 ODE Software Guidance, "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices" or IEC 60601-1-4.*

a) The latest software version is 2.01, released on March 6, 2001.

b) Pass/Fail criteria are attached as Amendment 1.

c) It is our assessment that the iScreen Digital Vision Screener meets the guidance requirements for a minor concern device. The only failure mechanism we can identify is the failure to acquire a readable image. In this case, the patient must return to the screening location for a re-screening. Since the device is a *screening tool*, no treatment is involved in the process, and the referring

physician takes care of diagnosis and treatment of each patient's vision. Additionally, there is no risk to the patient or user because of software. All electronics components are switched mechanically or electronically in the device (i.e. not with software). The software is used solely for the purpose of data entry and image acquisition (downloading and storage). Therefore, we believe we are in compliance with IEC 60601-1-4 or the May, 1998 ODE Software Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

6) *Please add the following prescription device caution to your labeling:*

"Caution: Federal law restricts this device to sale by or on the order of a Physician or Practitioner (CFR 801.109(b)(1))."

The Prescription Device Caution statement, given above, has been added to the device labeling.

7) *Labeling for Phototoxicity. Please add the following to your labeling (per ISO 10942).*

"WARNING: Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. This device should be used with filters that eliminate UV radiation (< 400 nm) and, whenever possible, filters that eliminate short-wavelength blue light (< 420 nm).

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

The Phototoxicity Warning label, given above, has been added to the device labeling.

We sincerely appreciate your assistance and attention to our submission.

Sincerely,

Peter Thrall, COO
iScreen™, LLC

Cc. Jack Bellows

Amendment 1 – Revised Pass/Fail Criteria

Table 1 – iScreen Software Modules with Pass/Fail Criteria (revised 4/16/01)

Library Module	Function	Pass	Fail
(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

March 19, 2001

ISCREEN, LLC
668 COLONIAL RD. (SUITE 1)
MEMPHIS, TN 38117
ATTN: PETER THRALL

510(k) Number: K010315
Product: ISCREEN VISION SCREENER

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 cite your 510(k) number and 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.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

If after 30 days the requested information, or a request for an extension of time, 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

Memorandum

From: Reviewer(s) - Name(s) Jan C Calloway

Subject: 510(k) Number K010315

To: The Record - It is my recommendation that the subject 510(k) Notification:

TH

☐ Refused to accept.

☒ Requires additional information (other than refuse to accept). telephone Ltr 3/16/01

☐ Is substantially equivalent to marketed devices.

☐ NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? ☐ YES ☒ NO

☐ 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
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ 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 N/A

☒ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

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

HKI 886.1120 Class II

Review: Gwendolyn T Bellamy DSDB 3/16/01
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Revised:8/17//99

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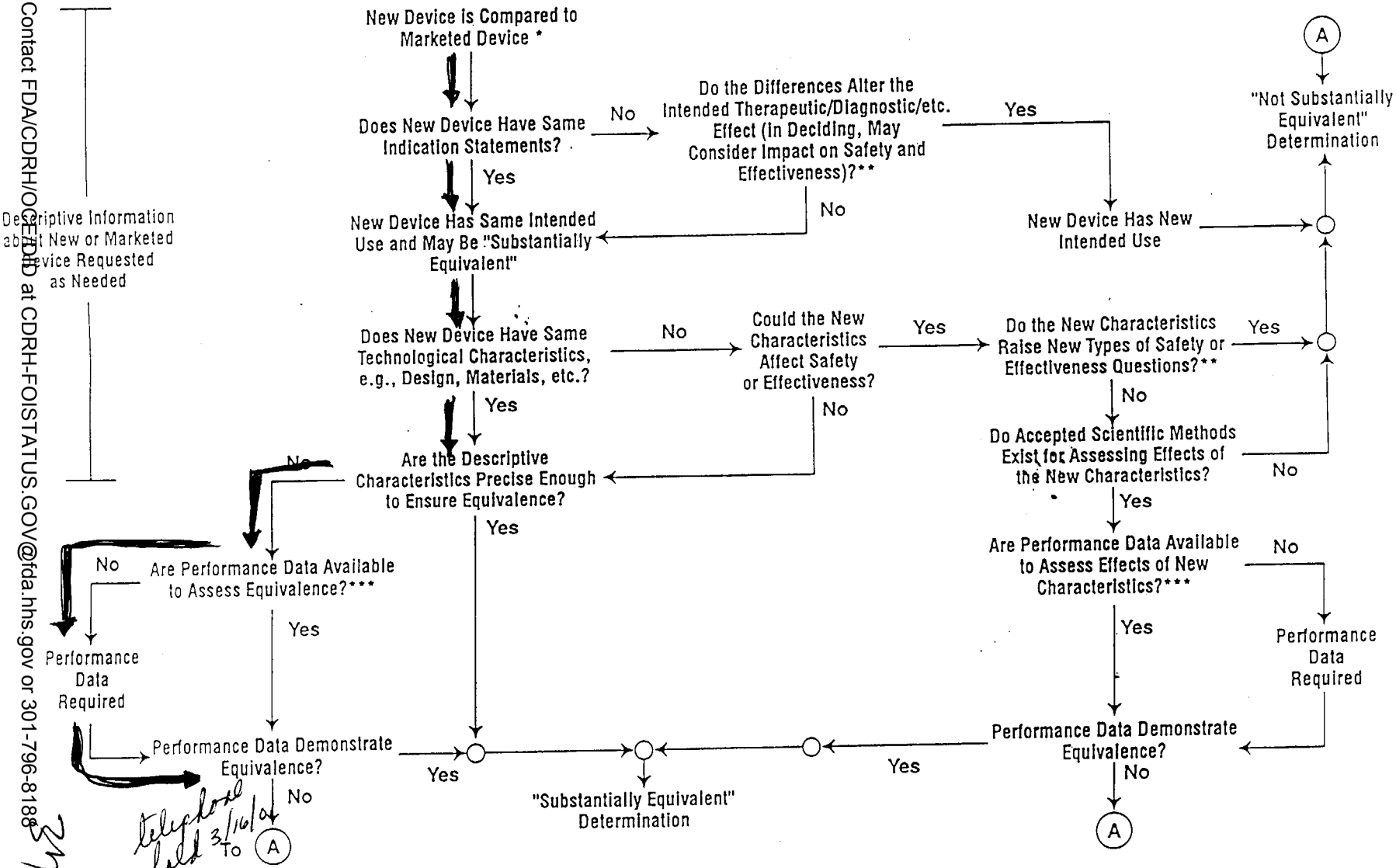
510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information If the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices Is Unclear.

** This Decision Is Normally Based on Descriptive Information Alone, But Limiting Information Is Sometimes Required.

*** Data May Be In the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

Telephoned 3/16/04 To

Questions? Contact FDA/CDRH/OCE/DD at CDRH-FOISTATUS.GOV@fda.hhs.gov or 301-796-8188

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name: iScreen Vision Screener | **K010315**

Submitter (Company): iScreen, LLC

Items which should be included *(circle missing & needed information)*	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5		

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	NA / YES / NO N/A						✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	SPECIALS YES	SPECIALS NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	
a) trade name, classification name, establishment registration number, device class					✓		
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				✓		
d) compliance with Section 514 - performance standards	NA				N/A		
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*					✓		
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*					N/A		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					✓		
k) Proposed Labeling:							
i) package labeling (user info)					✓		
ii) statement of intended use					✓		
iii) advertisements or promotional materials					✓		
i) MRI compatibility (if claimed)					N/A		
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:							
i) Labeling					✓		
ii) intended use					✓		
iii) physical characteristics					✓		
iv) anatomical sites of use					✓		
v) performance (bench, animal, clinical) testing	NA				✓		
vi) safety characteristics	NA				✓		
m) If kit, kit certification					N/A		

3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE				
a) Name & 510(k) number of legally marketed (unmodified) predicate device				
b) ***STATEMENT - INTENDED USE AND INDICATIONS***			* If no - STOP not a special	

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FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) ***STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED****			* If no - STOP not a special	
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable							

requirements or deviations noted below						
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed						
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device						
v) A specification of any deviations from each applicable standard that were applied						
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference						
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations						
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards						

5. Additional Considerations: (may be covered by Design Controls)					Yes	NO	Needed
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material					✓		
ii) identify patient-contacting materials					✓		
iii) biocompatibility of final sterilized product					N/A		
b) Sterilization and expiration dating information:					N/A		
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis						✓	
ii) level of concern						✓	
iii) development documentation					✓		
iv) certification							✓

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ **Yes** ____ **No**
Date: 3/15/01

Reviewer: Jan C Callaway
Concurrence by Review Branch: [signature]

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	
4. If, not, has POS been notified?	N/A	
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 010315

Reviewer: Jan C. Callaway

Division/Branch: DOED/DSDB

Device Name: iScreen Vision Screener

Product To Which Compared (510(K) Number If Known): K934880 and K951179

	YES	NO	
1. Is Product A Device	✓		If **NO** = Stop
2. Is 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?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use: The iScreen Vision Screener is a tool for screening vision problems in humans. It records and measures the retinal reflex and ocular status, providing data points for analysis and interpretation.

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. 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.

- The device is not life-supporting or sustaining, is not an implant or a kit, and does not contain a drug or biological product as a component. It is a prescription device.

- The iScreen system is made up of the screening unit, portable computer running Microsoft Windows 98, and interconnect cables. The iScreen software provides an easy interface for the user to enter patient information, and controls the digital and analog cameras in the screening device itself. The flash, fixation LED's and IR LED's are not software controlled, but are controlled by switching hardware. This design maximizes safety since all illumination sources are switched by the user or by hardware components and the software is used for data acquisition and storage. The photoflash is triggered by the CMOS camera using a standard low-voltage TTL circuit. IR LED's are switched by the IR camera power supply, and the fixation LED's are switched on by the user. The iScreen software does not allow users access to any other features or functions of the computer or operating system. When the user turns the computer on, the iScreen control software is launched. When the user exits the iScreen program, the software shuts down the computer. This increases reliability, eliminating potential problems or conflicts from unintended use of the computer.

  The iScreen program has 3 core modules:
  - Image Acquisition
  - Transmit Images
  - Analysis Results

- No part of the device is supplied sterile. The only component surface that comes in contact with the patient is the head rest. This component is curved to minimize the risk or injury. The head rest is made from molded unvulcanized rubber. This material does not present any significant biocompatibility issues.

- The iScreen Vision Screener belongs to a generic class of ophthalmic devices that utilize the techniques of eccentric photorefraction to record the retinal reflex and ocular status of the eye relying on human interpretation of data to determine the results of a screening.

  The iScreen Vision Screener is composed of two parts: 1) a camera system that records the retinal reflex and ocular status, and 2) a computer that stores the data for later interpretation.

This device in minimally invasive. A standard photographic flash is used to illuminate the face and eyes. The infrared (IR) camera uses light emitting diodes (LED's) to illuminate the patient with IR light in a dimly lit room.

The iScreen Vision Screener uses a 110VAC as a power source and employs an in-line transformer so that only 12VDC is supplied to the camera unit and 14VDC to the computer.

The device also employs a telemedicine capability by the transmission of images to a reading center. (b) (4)

(b) (4)

(b) (4)

Telephone hold on March 16, 2001: I sent a list of questions addressed to Mr. Peter Thrall by facsimile (attached) on March 15, 2001. I spoke with Ms. Alison Sykes on that day telling her that this action puts their document on telephone hold until they respond to the questions. Mr. Peter Thrall was not in, so she would give the facsimile to Mr. Jack Bellows.

RECOMMENDATION: This reviewer recommends that this document be placed on **telephone hold** until the applicant has officially responded to the questions sent to him by facsimile on March 15, 2001.

Jan C. Callaway

Jan C. Callaway

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

1. Explain why not a device: N/A

2. Explain why not subject to 510(k): N/A

3. How does the new indication differ from the predicate device's indication: N/A

4. Explain why there is or is not a new effect or safety or effectiveness issue: N/A

5. Describe the new technological characteristics: N/A

6. Explain how new characteristics could or could not affect safety or effectiveness: N/A

7. Explain how descriptive characteristics are not precise enough: (See attached March 15, 2001 memorandum to the company.)

8. Explain new types of safety or effectiveness questions raised or why the questions are not new: N/A

9. Explain why existing scientific methods can not be used: N/A

10. Explain what performance data is needed: (See attached March 15, 2001 memorandum to the company.)

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: N/A

ATTACH ADDITIONAL SUPPORTING INFORMATION

Memorandum

From: Everette T. Beers, Ph.D.
Subject: Review of K010315 iScreen

Deficiencies

Phototoxic Hazard

For comparing the ocular safety of one pulsed light source to another, it is necessary to compare the "effective retinal thermal radiant exposure" produced by the light sources. Thus, the irradiance data of the light sources for the device and a predicate provided in the submission is not sufficient to document the relative safety of the device.

Please provide a comparison of the "effective retinal thermal radiant exposure" for the device with a predicate device (see reference below). Alternatively, it may be possible to demonstrate equivalence for pulsed white light sources with similar spectral emissions by showing equivalence of the following parameters for the device and a predicate. The parameters include pulse width, spectral emissions, integrated radiant exitance (joules/cm^2) or integrated radiant intensity (joules/Sr), and the area illuminated on the retina.

Note: The weighting function for determining effective retinal thermal radiant exposure may be found in:

"2000 Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, American Conference of Governmental Industrial Hygienists, (ACGIH, Cincinnati, OH, 1996)". A copy of the booklet may be obtained for a fee from ACGIH. Telephone Number (513) 742-2020

Telemedicine

In your Instruction Manual, mention is made of transmitting images to a reading center. Please provide the following information regarding this aspect of the device:

1. Please provide a description of the method of communication with the reading centers. For instance, are these images sent by phone, wireless, Internet, etc.?

2. How is the "results information" returned to the referring physician?

3. Please describe any digitization schemes.

4. Please describe imaging (if appropriate) such as use of DICOM or JPEG standards.

5. Is any diagnostic software employed at the reading centers? If so, please refer to FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 29, 1998): www.fda.gov/cdrh/ode/software.pdf and "Off-

The-Shelf Software Use in Medical Devices" (September 9, 1999): http://www.fda.gov/cdrh/ode/otssguid.pdf

6. Security: HIPAA requires security of patient's records. Please describe security measures and certify conformance to some type of data security.

7. Electrical Safety: Please certify to, or declare of conformance to, a recognized electrical safety standard, such as International Electrotechnical Commission (IEC)-60601-1; include description of all sections to which conformance or certification is claimed and those that are not applicable.

The following guidance on Medical Image Management Devices may be helpful: "Guidance for the Submission of Premarket Notifications for Medical Image Management Devices" (July 27, 2000) www.fda.gov/cdrh/ode/guidance/416.pdf

with Phototor deficiencies
from DR. WANDRY, OST

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

CDRH
Division of Ophthalmic and Ear, Nose and Throat Devices

9200 Corporate Boulevard
Rockville, MD 20850
FAX NO. 301 480-4201
or 301 827-4601
PHONE NO. 301 594-2205

Date: 3/15/01 Time: 3:25 pm

To: Mr. Peter Thrall Fax #: 901-888-0072

Organization: iScreen, LLC

From: Jan Calloway

Department: DOED/DSDB

Subject: K010315

No. of Pages (Including cover sheet): 4

Comments:

☐ As Requested ☐ FYI ☐ Read and Destroy

☒ Response Needed ☐ Signature ☐ Circulate

☐ For Correction ☐ Investigate ☐ File

Division Director's Office	301 594-2205
Ear, Nose and Throat Devices Branch	301 594-2080
Diagnostic and Surgical Devices Branch	301 594-2018
Intraocular and Corneal Implants Branch	301 594-2053
Vitreoretinal and Extraocular Devices Branch	301 594-1744
Mail Code: HFZ 460	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: March 15, 2001

From: Jan C. Callaway, Scientific Reviewer (DOD/DSDB)
(301) 594-2018 FAX (301) 480-4201

Subject: Additional information for K010315
iScreen™ Vision Screener, iScreen™, LLC

To: Mr. Peter Thrall, Chief Operating Officer
(by fax to 901-888-0072 and by phone to 901-888-0071)

From my preliminary review of your application, the following additional information is needed. Please fax in your written response and any questions to the number above. After your response has been reviewed and considered acceptable, you will be asked to submit a hard copy to your file.

You may find the following guidance on Medical Image Management Devices may be helpful: "Guidance for the Submission of Premarket Notifications for Medical Image Management Devices" (July 27, 2000) www.fda.gov/cdrh/ode/guidance/416.pdf

1. For comparing the ocular safety of one pulsed light source to another to determine if there is any phototoxicity hazard, it is necessary to compare the "effective retinal thermal radiant exposure" produced by the light sources. Thus, the irradiance data of the light sources for the device and a predicate provided in the submission is not sufficient to document the relative safety of the device.

   Please provide a comparison of the "effective retinal thermal radiant exposure" for the device with a predicate device (see reference below). Alternatively, it may be possible to demonstrate equivalence for pulsed white light sources with similar spectral emissions by showing equivalence of the following parameters for the device and a predicate. The parameters include pulse width, spectral emissions, integrated radiant exitance (joules/cm2) or integrated radiant intensity (joules/Sr), and the area illuminated on the retina.

   Note: The weighting function for determining effective retinal thermal radiant exposure may be found in:

   "2000 Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, American Conference of Governmental Industrial Hygienists, (ACGIH, Cincinnati, OH, 1996)". A copy of the booklet may be obtained for a fee from ACGIH. Telephone Number (513) 742-2020

2. In your Instruction Manual, mention is made of transmitting images to a reading center. Please provide the following information regarding this aspect of the device:

   a) Please provide a description of the method of communication with the reading centers. For instance, are these images sent by phone, wireless, Internet, etc.?

   b) How is the "results information" returned to the referring physician?

   c) Please describe any digitization schemes.

   d) Please describe imaging (if appropriate) such as use of DICOM or JPEG standards.

   e) Is any diagnostic software employed at the reading centers? If so, please refer to FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 29, 1998): www.fda.gov/cdrh/ode/software.pdf and "Off-The-Shelf Software Use in Medical Devices" (September 9, 1999): http://www.fda.gov/cdrh/ode/otssguid.pdf

3. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires security of patient's records. Please describe security measures and certify conformance to some type of data security.

4. You must demonstrate electrical safety with bench testing, or declare conformance to an electrical safety standard recognized by FDA (e.g., International Electrotechnical Committee (IEC) 60601-1), or certify compliance with other electrical safety standards (e.g. Underwriters Laboratory (UL) 544, UL 2601-1, etc.; testing data may be required).

5. You have submitted documentation of your software functional test plan and validation, verification and testing. Please also submit the version number and date of your software and the pass/fail criteria. Please state whether your device complies with either the May, 1998 ODE Software Guidance, "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices" or IEC 60601-1-4.

6. Please add the following prescription device caution to your labeling:

   "Caution: Federal law restricts this device to sale by or on the order of a Physician or Practitioner" (CFR 801.109(b)(1))."

7. Labeling for Phototoxicity. Please add the following to your labeling (per ISO 10942):

   "WARNING: Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. This device should be used with filters that eliminate UV radiation (<400 nm) and, whenever possible, filters that eliminate short-wavelength blue light (<420 nm).

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography."

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	1716
CONNECTION TEL	919018880072
SUBADDRESS	
CONNECTION ID	
ST. TIME	03/15 16:19
USAGE T	03'06
PGS.	4
RESULT	OK

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CDRH
Division of Ophthalmic and Ear, Nose and Throat Devices

9200 Corporate Boulevard
Rockville, MD 20850
FAX NO. 301 480-4201
or 301 827-4601
PHONE NO. 301 594-2205

Date: 3/15/01 Time: 3:25pm

To: Mr. Peter Thrall Fax #: 901-888-0072

Organization: iScreen, LLC

From: Jan Calloway

Department: DOED/DSDB

Subject: K010315

No. of Pages (Including cover sheet): 4

Comments:

☐ As Requested ☐ FYI ☐ Read and Destroy

☒ Response Needed ☐ Signature ☐ Circulate

☐ For Correction ☐ Investigate ☐ File

Division Director's Office 301 594-2205

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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)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 02, 2001

ISCREEN, LLC
668 COLONIAL RD. (SUITE 1)
MEMPHIS, TN 38117
ATTN: PETER THRALL

510(k) Number: K010315
Received: 02-FEB-2001
Product: ISCREEN VISION SCREENER

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

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. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

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

K010515

Screen™
gital Vision Screening Technology

iScreen™ LLC
668 Colonial Road, Suite 1
Memphis, TN 38117
901-888-0071
Fax 901-888-0072
Toll free 888-873-6711
info@iscreenllc.com

January 31, 2001

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

Re: 510(k) Notification

Attention: Document Mail Clerk

This is to notify you of the intention of iScreen, LLC to market the following device:

Classification Name:	Ophthalmic Refractometer – Class I (510(k) exempt), Ophthalmic Camera – Class II
Common Name:	Ophthalmic Refractometer, Ophthalmic Camera
Proprietary Name:	iScreen Vision Screener
Classification Panel:	Ophthalmic

Establishment Registration Number: 2320749

Performance Standard with Section 514 or 513: We are unaware of any performance standards or special controls for this type of device.

Labeling and Promotional Material: Provided in the enclosed material.

Substantial Equivalence: This product is similar in intended use, design, and principles of operation to the MTI Photoscreener (K934880), and the Digital Retinoscopic Photometer (K951179).

In response to the requirements addressed by the CDRH, I am enclosing a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sincerely,

Peter Thrall
Chief Operating Officer
iScreen, LLC

enclosures

510(k) Elements List

510(k) Element	Page(s)	Comments
1. Device trade or proprietary name	2 and C1	
2. Device common or usual name and classification name	2 and C1	
3. Establishment registration number	1	
4. Class into which the device is classified under	2	
5. Classification Panel	2	
6. Action taken to comply with section 514 or the Act	2	No performance or special controls are currently in effect
7. Proposed labeling that describes the device, its intended use and directions for use	2, and Appendix A	
8. Statement of Indications for Use	2, and Appendix B	
9. A 510(k) summary of safety and effectiveness	Appendix C	510(k) summary provided
10. Class III certification	N/A	Class II device
11. Product illustrations	Appendix D	
12. Engineering drawings for the device	Appendix E	
13. The marketed devices to which equivalence is claimed including labeling and description of the device	3, and Appendix C	
14. Statement of similarities and/or differences with the marketed devices	3 – 4, and Appendix F	
15. Data to show consequences and effects of a modified device	Appendix F	
16. Submitter's name and address	1	
17. Contact person, telephone number and fax number	1	
18. Representative/Consultant	N/A	
19. Table of contents with pagination	Enclosed	
20. Address of manufacturing facility	1	
21. Action taken to comply with voluntary standards	N/A	
22. Comparison table of the new device to the marketed devices	Appendix F	
23. Performance data	N/A	
24. Sterilization information	N/A	
25. Software Information	Appendix H	
26. Hardware Information	Appendix E	

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27. If this 510(k) is for a kit, has the kit certification statement been provided?	N/A	
28. Is this device subject to issues that have been addressed in specific guidance document(s)?	N/A	
29. Statement of truthful and accurate information.	6	

Table of Contents

iScreen, LLC

iScreen Vision Screener

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[redacted]

510(k)
Premarket Notification

Screen
Digital Vision Screening Technology

510(k) Premarket Notification

for the iScreen, LLC

iScreen Vision Screener

January 31, 2001

The following information is being submitted in accordance with 21 C.F.R. § 807.87 for the iScreen Vision Screener, an ophthalmic refractometer and ophthalmic camera. The ophthalmic refractometer is a class I device which is exempt from 510(k) premarket notification (see 21 C.F.R. § 886.1760). Data and information on the ophthalmic camera is being submitted with this notification.

1. Submitter's Information:

Address: iScreen, LLC
668 Colonial Road, Suite 1
Memphis, Tennessee 38117
Phone: (901) 888-0071
Fax: (901) 888-0072
Contact Person: Peter Thrall, Chief Operating Officer

Peter Thrall, Chief Operating Officer
iScreen, LLC

Establishment Registration Number: (b) (4) [redacted]

Manufacturing Site:

The medical device will be manufactured by contract manufacturers that comply with iScreen, LLC designs and specifications, as well as applicable laws and regulations administered by the Food and Drug Administration. One such qualified subcontractor is (b) (4) [redacted]

(b) (4) [redacted]

(b) (4) [redacted]

2. Product Classification:

Trade Name: iScreen Vision Screener

Common Name: Ophthalmic Refractometer/Ophthalmic Camera

Device Class:

Ophthalmic Refractometer – Class I (510(k) exempt)
Ophthalmic Camera – Class II

Classification Regulations:

Ophthalmic Refractometer – 21 C.F. R. § 886.1760
Ophthalmic Camera – 21 C.F. R. § 886.1120

Classification Panel: Ophthalmic

3. Action Taken to Comply With Section 514 or 513 of the Act:

We are unaware of any performance standards or special controls for this type of device.

4. Proposed Product Labeling Sufficient to Describe Intended Use and Directions for Use:

A copy of the proposed Instruction Manual appears at Appendix A.

For vision screening reports being returned to the patient or family member, the following labeling is proposed:

This report is for vision screening purposes only and is not intended to be a substitute for a complete eye examination. Vision screening is intended to identify, with a reasonable degree of accuracy, people who may have vision problems. Since vision changes can occur without you or your child noticing them, we recommend that your child visit an eye care specialist at least every two years.

5. Indications for Use Statement:

The iScreen Vision Screener is a tool for screening vision problems in humans. It records and measures the retinal reflex and ocular status, providing data points for analysis and interpretation.

The Indications for use Form also appears at Appendix B.

6. 510(k) Summary:

A 510(k) summary is enclosed as part of this submission as required by 21 C.F.R. § 807.92. See Appendix C.

7. Photographs of the Device:

See Appendix D.

8. Engineering Drawings of the Device:

Schematic diagrams, engineering drawings, and a list of components are attached at Appendix E. These documents are marked "Confidential" and are exempt from public disclosure under 21 C.F.R. Part 20, Section 301(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), and Title 5 of the Administrative Procedures Act ("APA").

9. Legally Marketed Devices to Which Equivalence is Claimed:

- MTI Photoscreener (K934880)
- Digital Retinoscopic Photometer (K951179)

10. Statement of Similarities and/or Differences with the Marketed Device:

The iScreen Vision Screener belongs to a generic class of ophthalmic devices that utilize the technique of eccentric photorefraction to record the retinal reflex and ocular status of the eye. This is the same technique used by the MTI Photoscreener (K934880), Digital Retinoscopic Photometer (K951179), and other Ophthalmic Refractometer/Camera devices.

Both the MTI Photoscreener and iScreen Vision Screener rely on human interpretation of data to determine the results of a screening. Although the manufacturer of the Digital Retinoscopic Photometer does not claim differential diagnostic capability, the system employs computer algorithms to measure image parameters useful in assessing preliminary indications of vision problems. The MTI Photoscreener and iScreen Vision Screener employ a fixation component made up of blinking light emitting diodes (LED's) and an audible sound to attract the patient's attention so that they fixate very close to the camera.

The iScreen Vision Screener is composed of two parts: 1) a camera system that records the retinal reflex and ocular status, and 2) a computer that stores the data for later interpretation.
The camera system is similar to any ophthalmic camera, being comprised of a housing for components, a digital camera for recording the retinal reflex and ocular status, a flash system for generating light, a fixation device for attracting the patient's attention and an alignment camera that helps the user position the patient very accurately. The digital camera is becoming widely used in nearly all aspects of medical imaging. The light source used in this device is a standard photographic flash that is fitted with an attenuator that shapes the beam in to a line of light. The attenuating mask is a small aluminum plate with a 3 mm X 10 mm slot, restricting the output area to roughly 5% of the original. The intensity of light is attenuated to 2.04×10^{-6} W/cm^2, which is much less than standard off-the-shelf photoflash equipment.

The iScreen Vision Screener records a color image using a Complimentary Metal-Oxide Semiconductor (CMOS) digital camera. The MTI Photoscreener and Digital Retinoscopic Photometer both record grayscale images. The MTI device uses a Polaroid™ camera and the Digital Retinoscopic Photometer uses a Charge Coupled Device (CCD) camera.

The iScreen Vision Screener also uses an infrared camera to assist in aligning the patient in a dimly lit room. The use of color imaging, and an infrared camera for patient positioning are not significantly different, and do not affect the primary purpose or function of the device.

The Digital Retinoscopic Photometer and iScreen Vision Screener both use 110VAC as a power source. However, the iScreen Vision Screener employs an in-line transformer so that only 12VDC is supplied to the camera unit and 14VDC to the computer. The MTI Photoscreener is a battery-powered unit.

All eccentric photorefractors are marketed for similar purposes. Since a system employing this technique does not require verbal response from the patient, it can be used to screen patients of all ages for vision problems, and becomes particularly useful for young children.

11. Product Description and Comparison Table of the Device to the Marketed Devices:

See Appendix F.

12. Biocompatibility Information:

The only component surface that comes in contact with the patient is the head rest. This component is curved and made of a flexible rubber compound to minimize the risk of injury. The head rest material does not present any significant biocompatibility issues.

This device is minimally invasive. A standard photographic flash is used to illuminate the face and eyes. This flash unit is fitted with an attenuator that shapes the beam in to a line of light. The attenuating mask is a small aluminum plate with a 3 mm X 10 mm slot, restricting the output area to roughly 5% of the original. The intensity of light is attenuated to 2.04×10^{-6} W/cm^2, which is much less than standard off-the-shelf photoflash equipment. The infrared (IR) camera uses light emitting diodes (LED's) to illuminate the patient with IR light in a dimly lit room. The intensity of these LED's is 8.76×10^{-7} W/cm^2. The fixation device uses red LED's with very low intensity. Only about 10% of the light from the fixation LED's is reflected from the beam splitter.

A report confirming the biocompatibility of the plastic insulating material (cytotoxicity) and illumination intensity is also included at Appendix G.

13. Safety and Effectiveness Statement

To assure that the device is safe and effective, all finished devices are tested and must meet all required release specifications before distribution. The testing required for release includes, but is not limited to the following:

- Camera
    1. Printed Circuit board
        a. Power distribution to electronic components
        b. Fixation LED's
    2. Wiring harness
    3. Photoflash
        a. Charging circuitry
        b. Intensity
        c. Alignment
    4. Digital camera

a. Focus
b. Aperture
c. Alignment

5. IR camera
   a. Focus
   b. Alignment
6. Image quality
7. Mechanical integrity

- Computer
  8. Cabling
  9. Communications with camera device
  10. Software functionality

The required testing is defined by written and approved procedures that conform to the device design specifications.

14. Sterilization Information:

Not applicable.

15. Software Information:

See Appendix H.

16. Specific Guidance Document:

Not applicable.

17. Truthful and Accurate Statement:

[As required by 21 C.F.R. § 807.87 (j)]

I certify that, in my capacity as Chief Operating Officer of iScreen, LLC, I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Peter Thrall, Chief Operating Officer
iScreen, LLC
January 31, 2001

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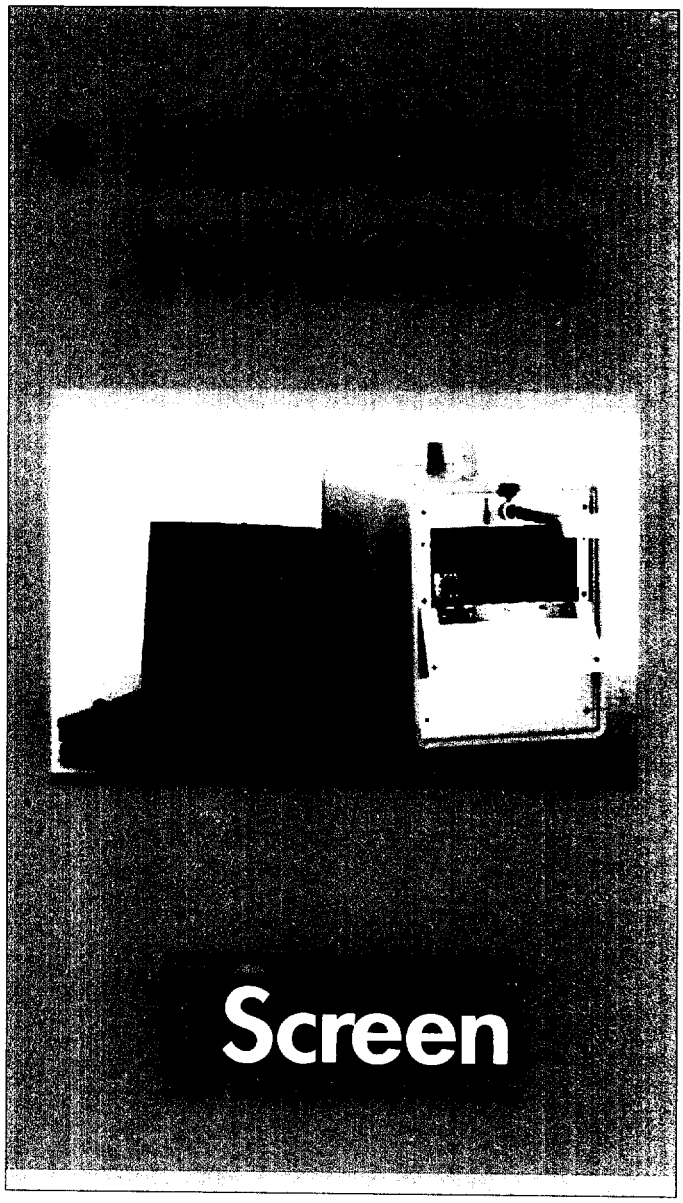
[redacted]

Appendix A

iScreen Vision Screener Instruction Manual

Screen
Digital Vision Screening Technology



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Safety Guidelines

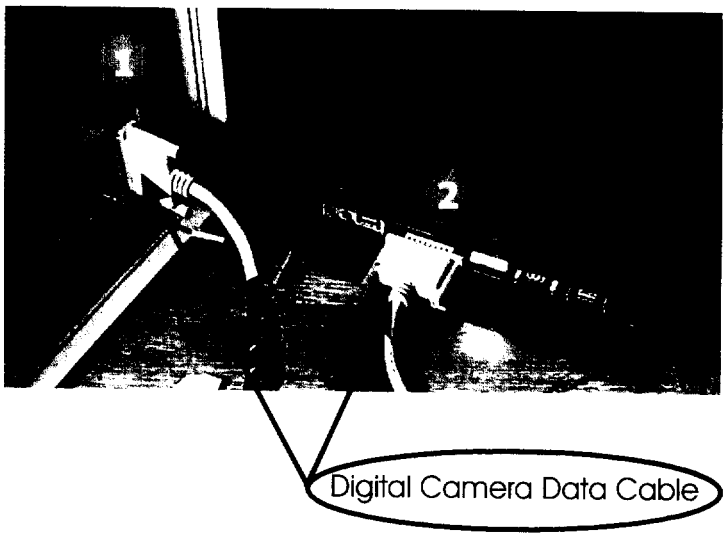
The iScreen system is engineered to be durable and easy to use, but please keep in mind that there are sensitive electronic components inside the unit. To maintain a safe environment for yourself and your patients, and to promote a long life for the unit, please follow the guidelines listed below:

- Never extend your arm inside the front window of the iScreen unit.
- Never place liquids or chemicals around the portable computer or the iScreen unit.
- Identify and use the correct power supply for the iScreen unit and the computer. Never try to switch the power supplies.
- When disconnecting or reconnecting cables, always grip the connector - never pull on the cable itself.
- Make sure that the laptop and iScreen unit are placed securely on a table and wires are out of the way. Loose wires can cause tripping. Make sure that the computer cannot be accidentally pulled off the table.

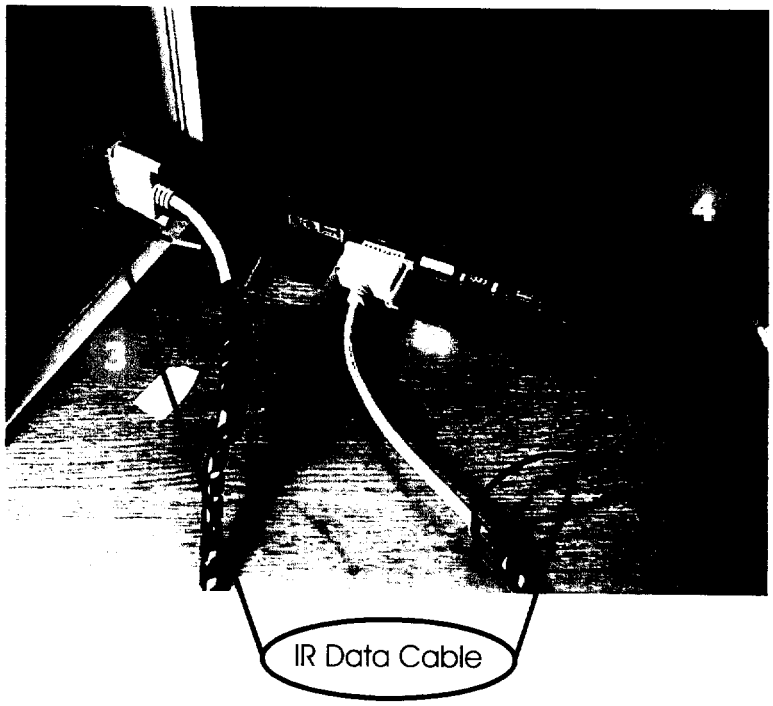
• Connecting Cables

To connect the iScreen unit to the computer, follow the steps below. The communication cables connecting the computer to the iScreen unit are color-coded.

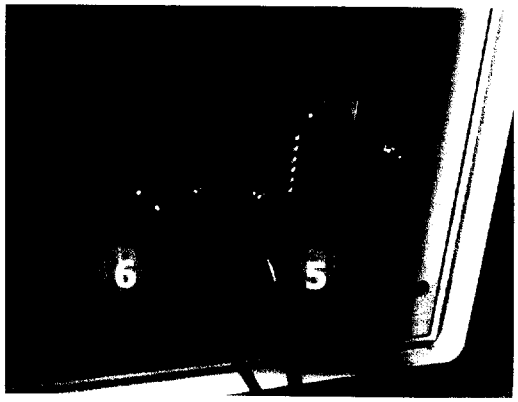
- Connect the digital camera data cable (the cable with the white jacket) to the iScreen unit and the computer. Please note that the cable has a male and a female connector. The female connector attaches to the 25-pin data port on the rear of the iScreen unit. The male connector attaches to the parallel (printer) port on the back of the computer. Tighten the two thumbscrews on each connector securely.



- Connect the infrared (IR) data cable (bundled with the white digital camera cable) to the IR data port (black) on the rear of the iScreen unit. The other end of the IR data cable has a triangular connector that attaches to the video card on the left side of the computer. Make sure that the logo on the connector (the letters "AMP") is facing up. Pinch the metal tabs together and gently push the connector into the video card. Release the metal tabs.

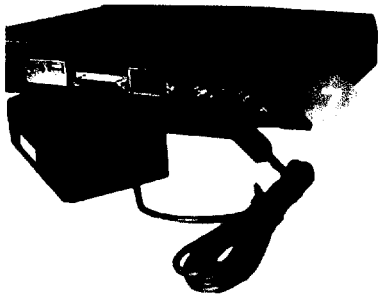


- Insert the foot switch plug into the blue connector on the rear of the iScreen unit.



- Attach the iScreen power plug into the red connector on the rear of the iScreen unit.

- Attach the computer power plug into the rear of the computer.



- Plug the iScreen power supply and computer power supply into a wall outlet or approved power strip. Each power supply has a unique power cord.

- Turn on the iScreen unit; wait a few seconds, then turn on the computer.

Note: the iScreen unit must be turned on before turning on the laptop computer.

- Connect one end of the phone cable to the laptop computer and the other end to a wall-mounted phone jack. If you are using a wireless modem, call technical support and they will walk you through the setup procedure.

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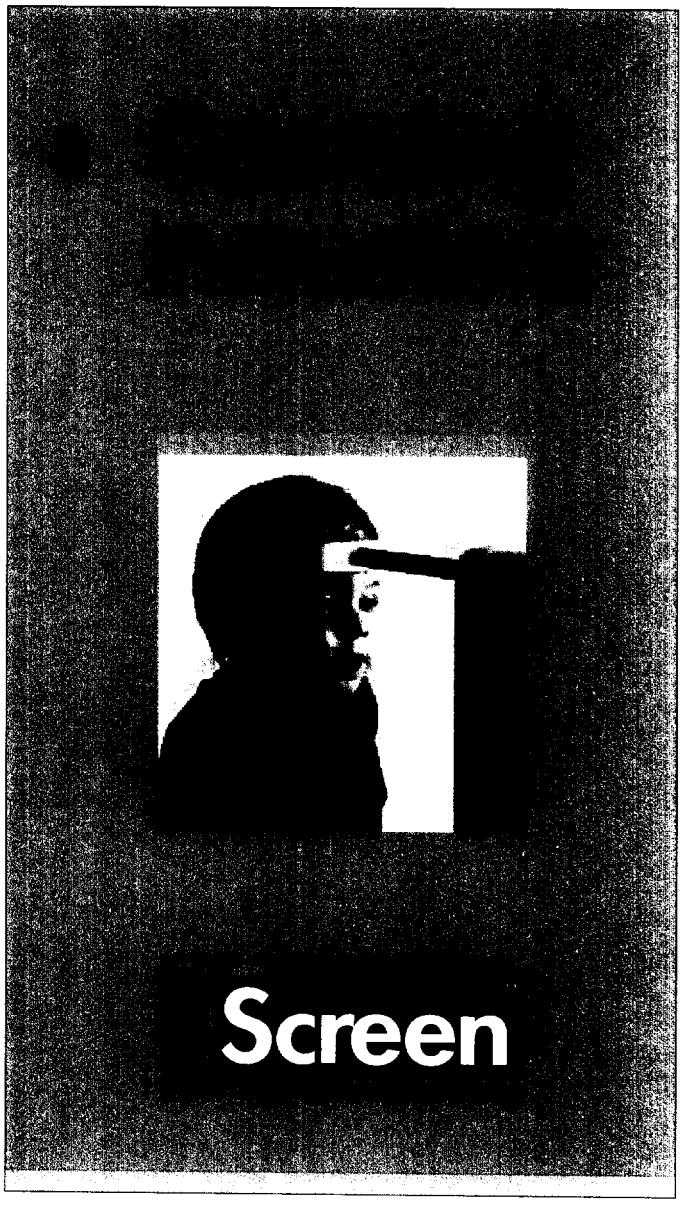

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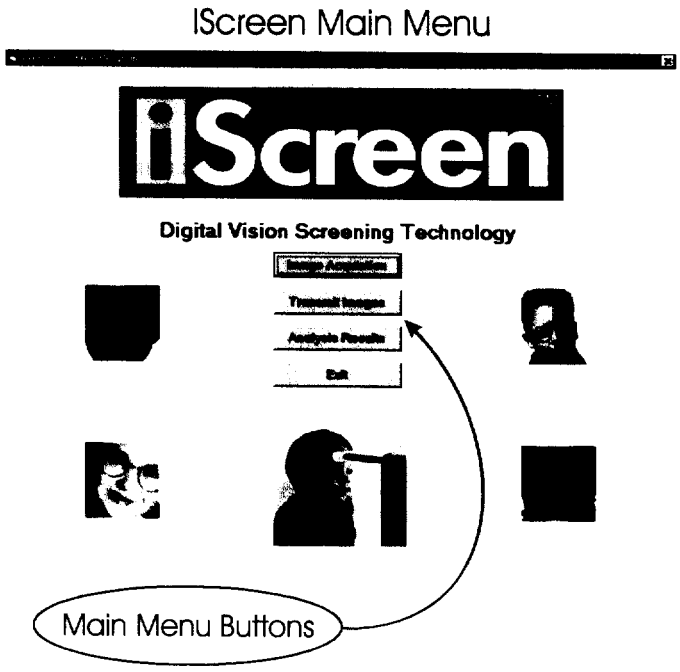
• Using the iScreen Software

When you turn on the computer, the iScreen main menu will appear on your screen. There are four options on the main menu. You can select an option by using the mouse to press one of the buttons located in the center of the screen.



• Main Menu Options

1. Pressing the *Image Acquisition* button will take you through the process of acquiring an image for vision screening.

2. Pressing the *Transmit Images* button will send images to a reading center.

Your computer is already set up to transmit images at night or at regular intervals during the day, so you will not need to use the Transmit option unless you want to send images immediately.

3. Pressing the *Analysis Results* button allows you to see the status and results of images you have acquired.

4. Pressing the *Exit* button will shut down the computer.

• Image Acquisition
Patient Information

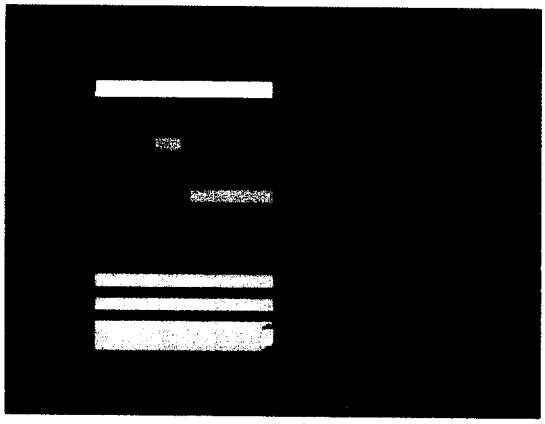
The following steps will guide you through the process of acquiring a digital screening image.

1. From the iScreen main menu, press the *Image Acquisition* button.

2. Type in the required patient information. Use the *Enter* key to move between fields. The following sequence outlines each step:

   - Type the patient's name and press the *Enter* key.
   - Type the patient's ID (usually the chart number) and press the *Enter* key.

Patient Information Screen



- Type the patient's age (years) and press the *Enter* key. If the patient is less than 2 years old, the months field will brighten. Enter a value for months, or a dash if unknown.

- Select the patient's gender by pressing the up or down arrow keys. You can also pull down the options by moving the mouse over the field and pressing the left mouse button. Press the *Enter* key to move to the next field.

- Select the patient's race using the up or down arrow keys or the mouse. Press the *Enter* key to move to the next field. If you choose "Other," the Other Race field will brighten. Type the patient's race in this field and press the Enter key.

- Choose an option from the Family History - Refractive Error field. Use the up or down arrow keys or the mouse to make a selection. Press the *Enter* key to continue.

- Do the same for the patient's family history of cataracts. Press the *Enter* key to continue.

At this point, the NEXT button will brighten. You can continue entering optional information or you can press the NEXT button to go the Patient Alignment screen.

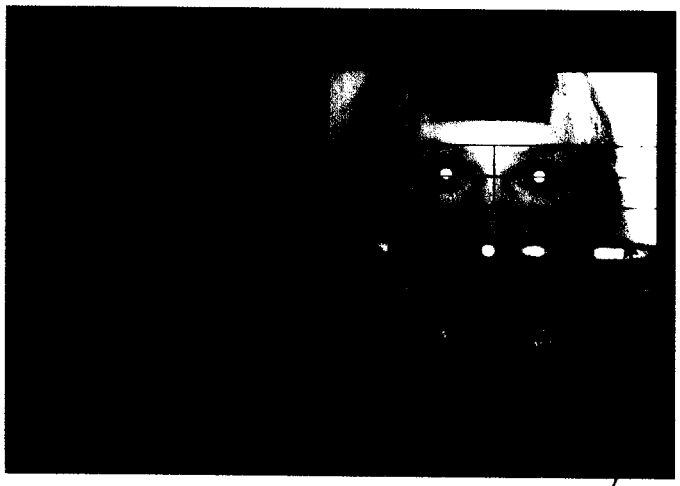
- Enter optional information in the remaining three fields: Physician, SSN, and comments. Press the *Enter* key to move between fields.

• Image Acquisition
Patient Alignment

3 When you press the *NEXT* button on the Patient Information screen, you will proceed to the Patient Alignment screen. An alignment camera in the iScreen unit provides a black and white image of the patient in the upper right corner of the computer screen.

For accurate vision screening, it is important that the eyes be as close to the center of the camera as possible. Use the video image in the Patient Alignment screen to assist in aligning the patient.

Patient Alignment Screen



- Gently position the patient's forehead secure against the headrest, and adjust the vertical and horizontal position of the patient until the eyes are centered on the cross hairs in the video image on the Patient Alignment screen.

The patient alignment camera uses infrared light to illuminate the patient in a dimly lit room. The infrared light also makes the pupils appear very bright as seen in the picture below. Use the contrast of the pupils to assist in aligning the patient.

- When the patient is aligned and looking into the camera, press the *ACQUIRE IMAGE* button. To help get the patient's attention, the fixation lights can be activated by depressing the foot switch.

It may be useful to move the mouse over the Acquire Image button prior to aligning the patient. Then the left mouse button can be used as a trigger to quickly capture an image as soon as the patient is aligned and looking into the camera.

Patient Alignment Video Image

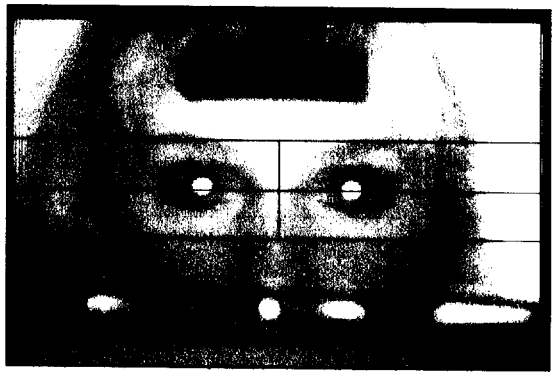


Image Acquisition
Review Image

4 When you press the *ACQUIRE IMAGE* button, the digital camera will capture an image of the patient and download the image to the laptop computer. The image will appear on the screen in about 10 seconds.

- Review the image to make sure that the patient is looking directly into the lens (fixated properly), and the eyes are unobstructed.

- If the patient is not fixated properly, or the eyes are obstructed, the image cannot be analyzed accurately. Press the *RE-ALIGN PATIENT* button.

- Press the *SAVE* button to save the image; the image will be sent automatically to a reading center..

It is much easier to take another image than to re-schedule a patient's exam.

Review Image Screen

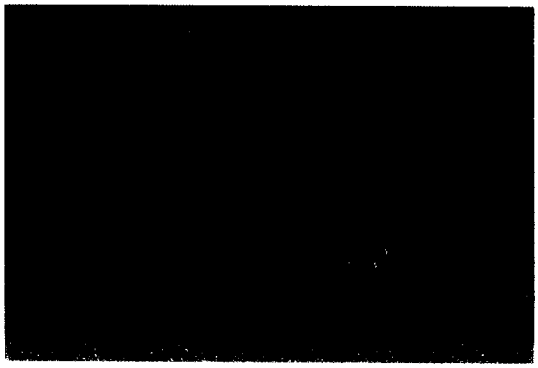


Image Acquisition

Patient Fixation

One way to determine if the patient is fixated properly is to observe the bright white spot in the center of the eye (called the corneal reflex) and check its location within the pupil.

If a patient is fixated correctly, the bright white reflections will be close to the center of the pupil. If the patient is not fixated properly, the bright white reflections will be to one side of the pupil.

Reflection centered in pupil (good fixation)

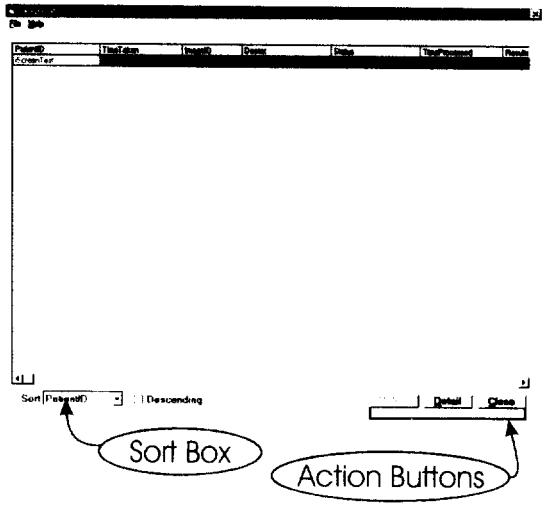
Reflection at edge of pupil (bad fixation)

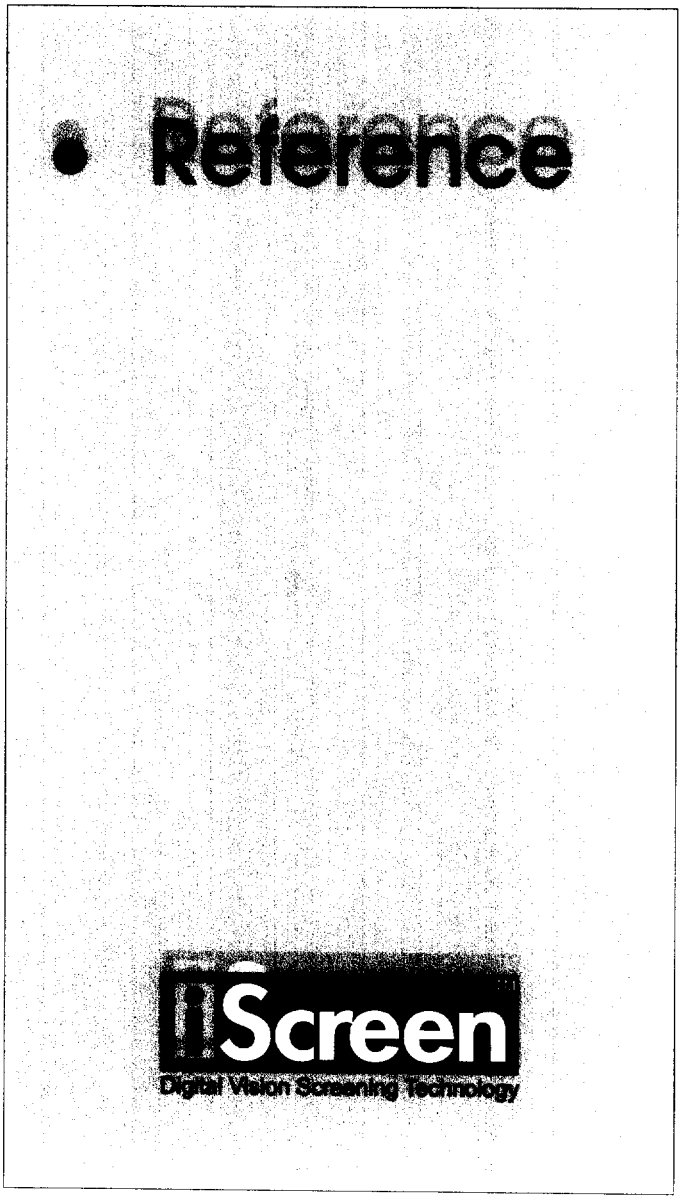
Analysis Results

Information about the status of each image can be seen by pressing the *Analysis Results* button on the Main Menu. The status column shows the progress of each image. Results are updated each time the computer connects to the reading center.

- Results can be sorted by Time, Doctor, Status, or any of the other column headings using the Sort pull-down box in the lower left corner of the screen.
- To see details of the patient information, select an image record and press the *Detail* action button.
- Press the *Close* button to return to the Main Menu.

Analysis Results Screen





A17

iScreen Technical Support

You can reach iScreen support staff during normal business hours by any of the means listed below.

Address: 668 Colonial Road, Suite 1
Memphis, TN 38117

Phone: 901-888-0071
Fax: 901-888-0072
Toll free: 888-873-6711

Email: support@iscreenllc.com
Information: info@iscreenllc.com

Visit our Web site at www.iscreenllc.com.

iScreen™
Digital Vision Screening Technology

Installation Checklist

To be completed and signed by both the client and sales representative.

- ☐ Training has been completed for all staff operating the iScreen unit.
- ☐ Client information on the computer is correct. Sample image was transmitted, analyzed, and the report received correctly.
- ☐ Client understands the criteria for normal and abnormal analysis of digital images, and has been shown recommended guidelines for vision screening.
- ☐ Everyone using the iScreen system has been instructed in how to find support information:
  - Technical Support phone numbers
  - User manual
  - Reference Literature

The undersigned agrees that the sales representative has fully complied with the guidelines listed above.

Client Signature	Sales Rep. Signature
Date	Date

Appendix B

Indications for Use

iScreen™
Digital Vision Screening Technology

510(k) Number (if known): K010315

Device Name: iScreen Vision Screener

Indications For Use:

The iScreen Vision Screener is a tool for screening vision problems in humans. It records and measures the retinal reflex and ocular status, providing data points for analysis and interpretation.

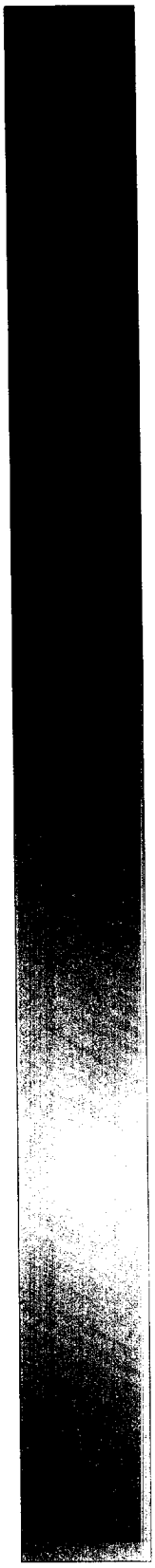
(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K010315

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

B1



Appendix C

510(k) Summary

iScreen™
Digital Vision Screening Technology

510(k) Summary

[As required by 21 C.F.R. § 807.92 (c)]

January 31, 2001

Submitter's Name: iScreen, LLC
668 Colonial Road, Suite 1
Memphis, Tennessee 38117
Phone: (901) 888-0071
Fax: (901) 888-0072

Contact Person: Peter Thrall, Chief Operating Officer

Device Trade Name: iScreen Vision Screener

Common Name: Ophthalmic Refractometer/Ophthalmic Camera

Classification Regulations:
Ophthalmic Refractometer – 21 C.F. R. § 886.1760
Ophthalmic Camera – 21 C.F. R. § 886.1120

Legally Marketed Device to Which Equivalence is Claimed:

- MTI Photoscreener (K934880)
- Digital Retinoscopic Photometer (K951179)

Description of the Device:

The iScreen Vision Screener belongs to a generic class of ophthalmic devices that utilize the technique of eccentric photorefraction to record the retinal reflex and ocular status of the eye. All of these instruments have similar primary components: 1) an illumination source, and 2) a recording device. These instruments project a beam of light onto the face and eyes of a patient. The recording device, typically a digital or film-based camera, records an image of the retinal reflex, sometimes called the "red reflex." The retinal reflex provides indications of the ability of the eye to focus light. The ocular status is also recorded in the same image

since any degradation of the optics of the eye that would affect vision will also degrade the beam of light generated by the illumination source.

Similarly, the iScreen Vision Screener system is composed of two parts: 1) a camera unit that records the retinal reflex and ocular status, and 2) a computer that stores the data for later interpretation. The camera unit and computer are powered by a transformer that plugs into a standard 110 VAC wall outlet. The camera unit is supplied with 12 VDC and the computer with 14 VDC. The camera unit is similar to any ophthalmic camera, being comprised of a housing for components, a digital camera for recording the retinal reflex and ocular status, a flash system for generating light, a fixation device for attracting the patient's attention and an alignment camera that helps the user position the patient very accurately. The digital camera is becoming widely used in nearly all aspects of medical imaging. The light source used in this device is a standard photographic flash that is fitted with an attenuator that shapes the beam in to a line of light. The attenuating mask is a small aluminum plate with a 3 mm X 10 mm slot, restricting the output area to roughly 5% of the original. The intensity of light is attenuated to 2.04×10^{-6} W/cm^2, which is much less than standard off-the-shelf photoflash equipment.

Summary of Intended Use:

The iScreen Vision Screener is a tool for screening vision problems in humans. It records and measures the retinal reflex and ocular status, providing data points for analysis and interpretation.

Summary of Technological Characteristics of the iScreen Vision Screener as Compared to the Predicate Devices:

The iScreen Vision Screener is very similar in function and purpose to the MTI Photoscreener (K934880), Digital Retinoscopic Photometer (K951179), and Ophthalmic Refractometer/camera devices. All of these devices use an illumination source and camera to record and measure the retinal reflex and ocular status. The MTI Photoscreener and Digital Retinoscopic Photometer record grayscale images, while the iScreen Vision Screener records a color (24 bit) image. The Digital Retinoscopic Photometer and the iScreen Vision Screener record images with a digital camera, which are subsequently transferred to a computer. The MTI Photoscreener is a film-based system, using a Polaroid™ camera to record information. Both the MTI Photoscreener and iScreen Vision Screener rely on human interpretation of the results of the photoscreening image, whereas the Digital Retinoscopic Photometer uses computer algorithms to measure image parameters.

Both The MTI Photoscreener and iScreen Vision Screener employ a fixation component made up of blinking light emitting diodes (LED's) and an audible sound to attract the patient's attention so that they fixate very close to the camera. The iScreen Vision Screener also uses an infrared camera to assist the user in positioning the patient in a dimly lit room. The use of an infrared camera for patient positioning is not significantly different, and does not affect the primary purpose or function of the device.

The Digital Retinoscopic Photometer and iScreen Vision Screener both use 110VAC as a power source. However, the iScreen Vision Screener employs an in-line transformer so that only 12VDC is supplied to the camera unit and 14VDC to the computer. The MTI Photoscreener is a battery-powered unit.

All eccentric photorefractors are marketed for similar purposes. Since a system employing this technique does not require verbal response from the patient, it can be used to screen patients of all ages for vision problems, and becomes particularly useful for preverbal children.

Safety and Effectiveness Statement

To assure that the device is safe and effective, all finished devices are tested and must meet all required release specifications before distribution. The testing required for release includes, but is not limited to the following:

- Camera
    1. Printed Circuit board
        a. Power distribution to electronic components
        b. Fixation LED's
    2. Wiring harness
    3. Photoflash
        a. Charging circuitry
        b. Intensity
        c. Alignment
    4. Digital camera
        a. Focus
        b. Aperture
        c. Alignment
    5. IR camera
        a. Focus
        b. Alignment
    6. Image quality

7. Mechanical integrity

- Computer
  8. Cabling
  9. Communications with camera device
  10. Software functionality

The required testing is defined by written and approved procedures that conform to the device design specifications.

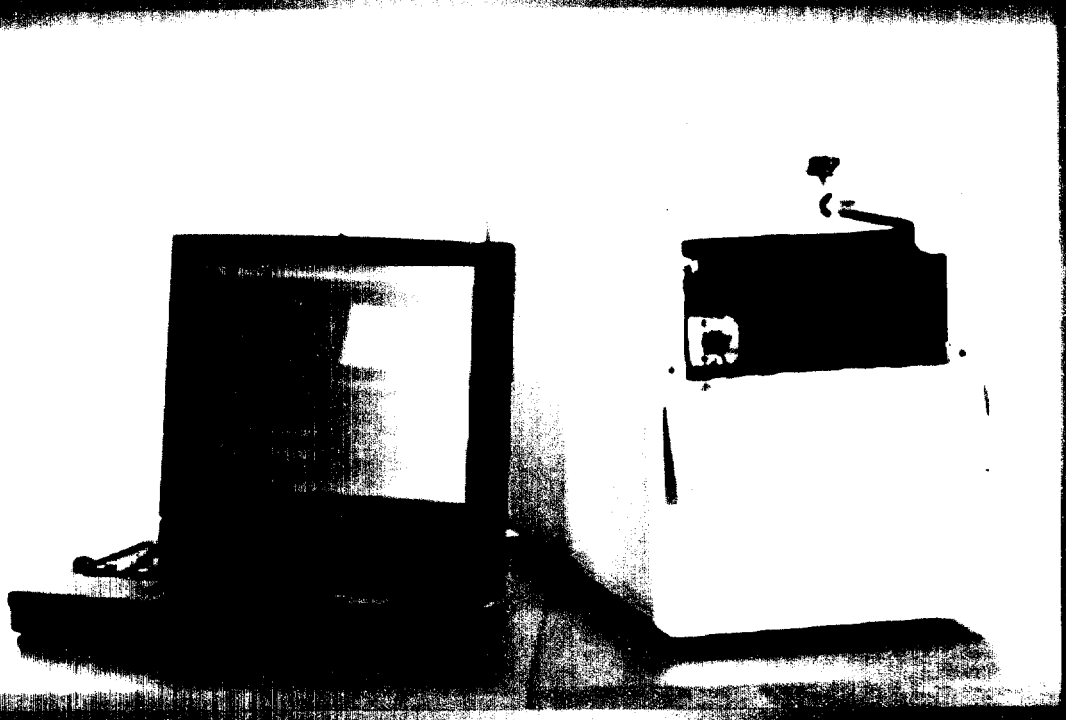
Appendix D

Photographs of the Device

iScreen™
Digital Vision Screening Technology

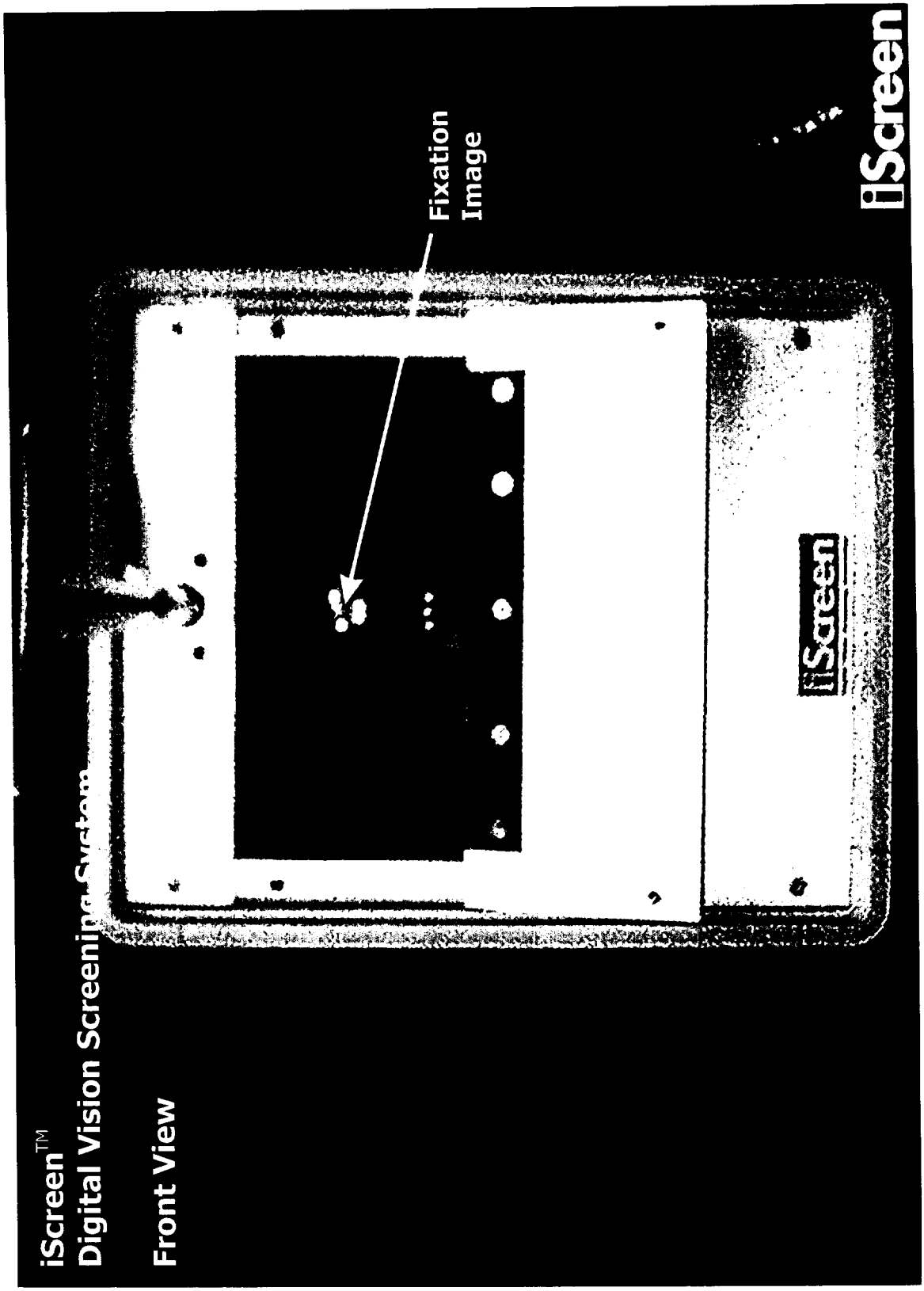
Digital Vision Screening Technology

Device Photographs

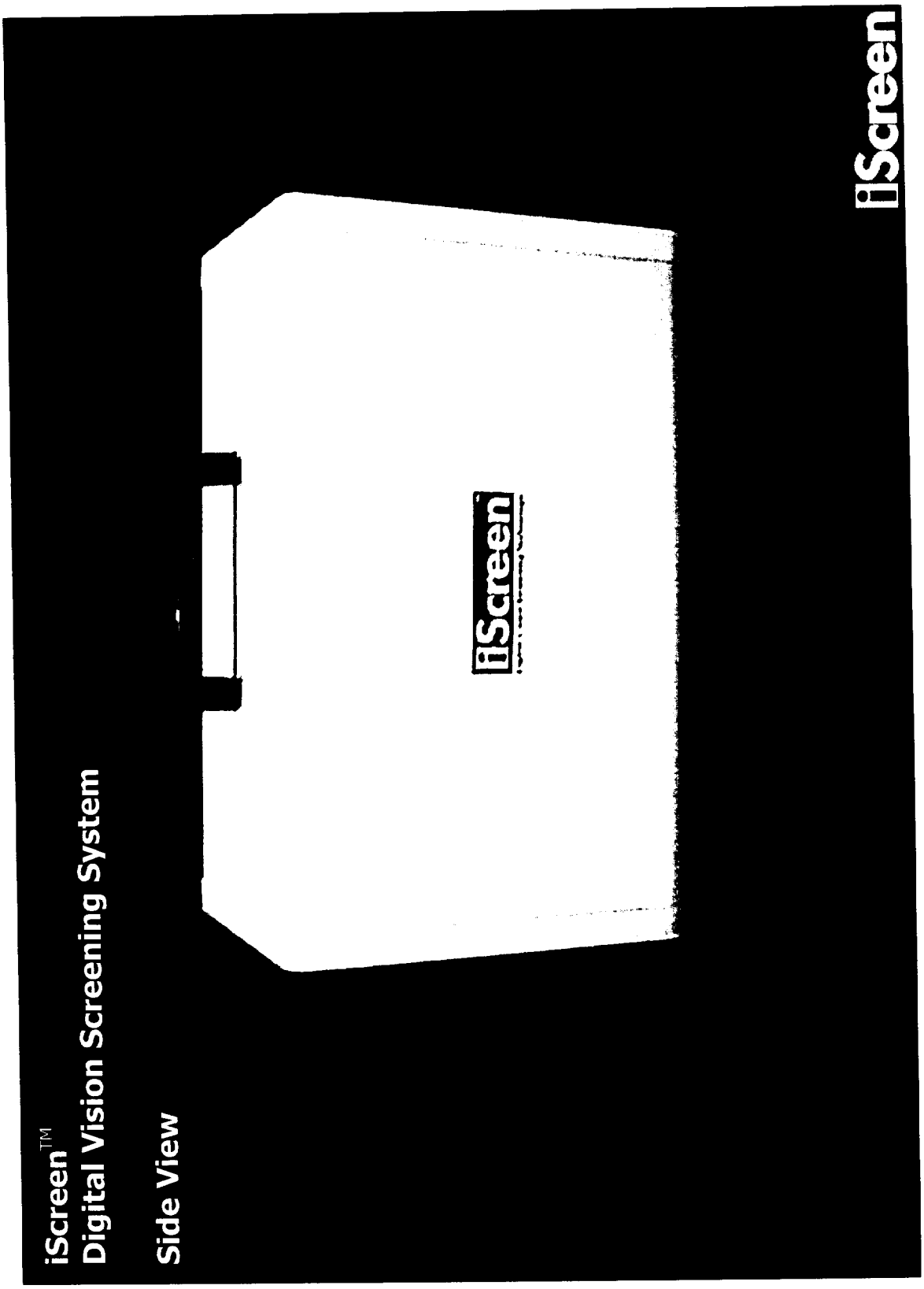


iScreen™

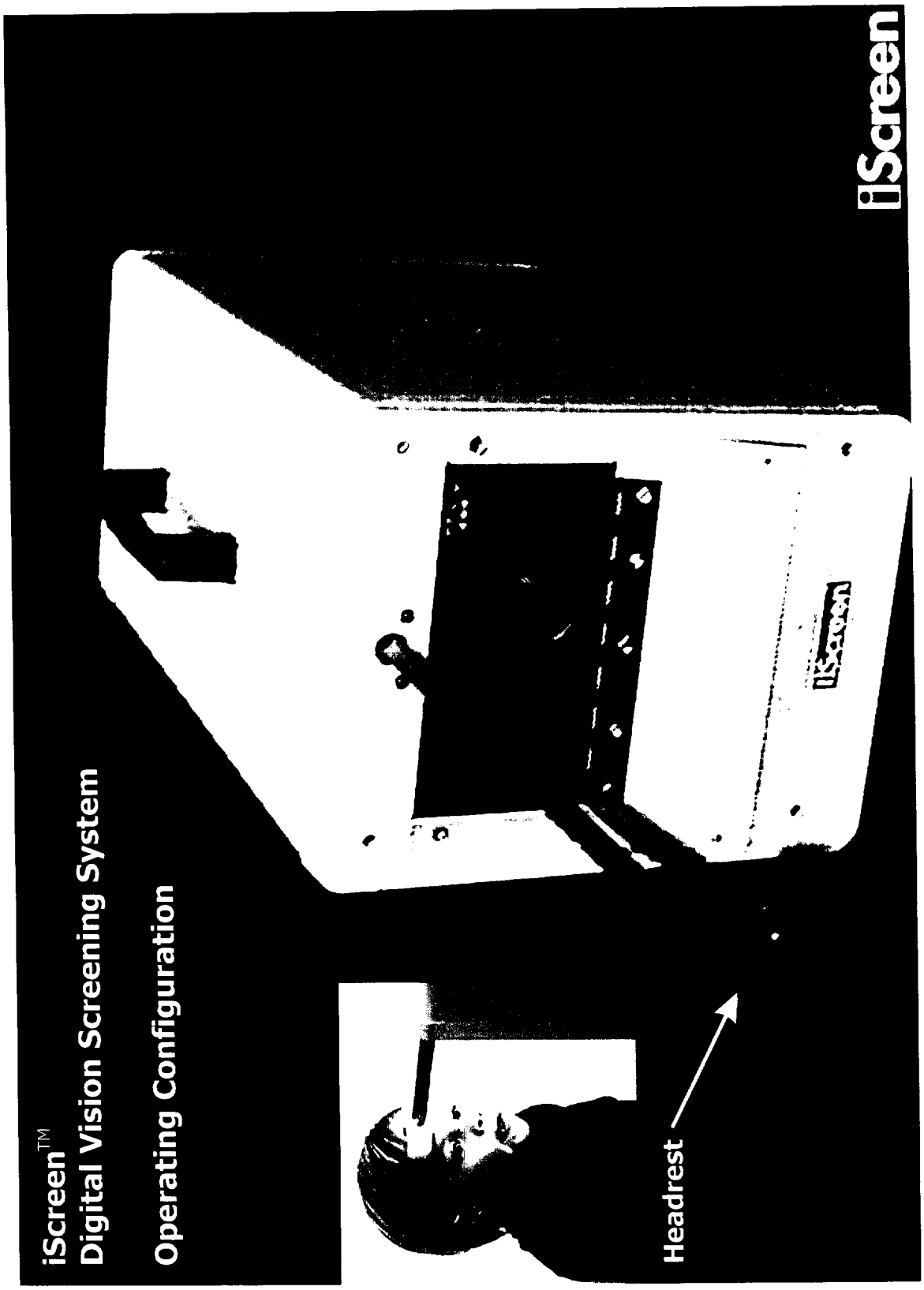
D1

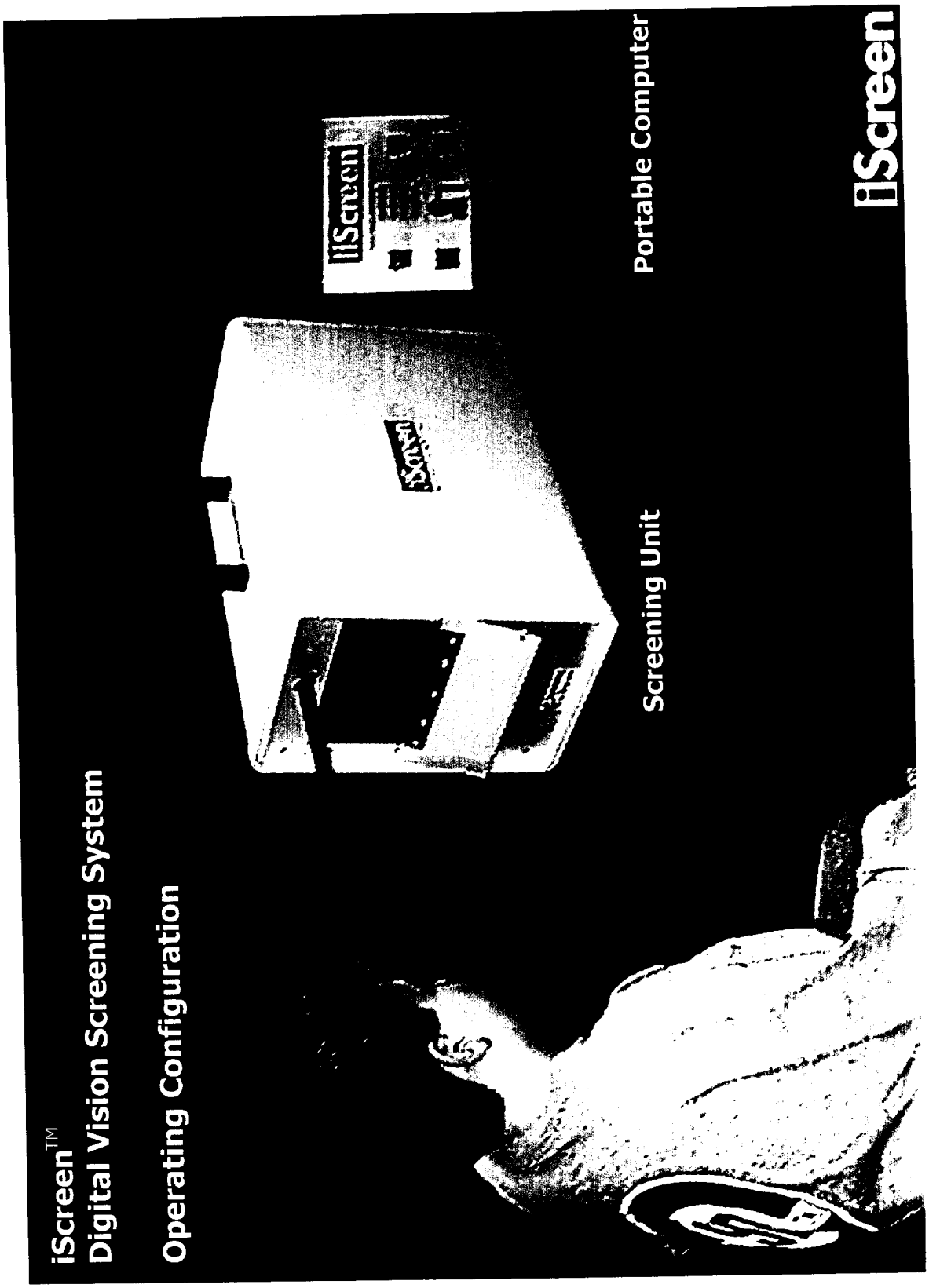


D2

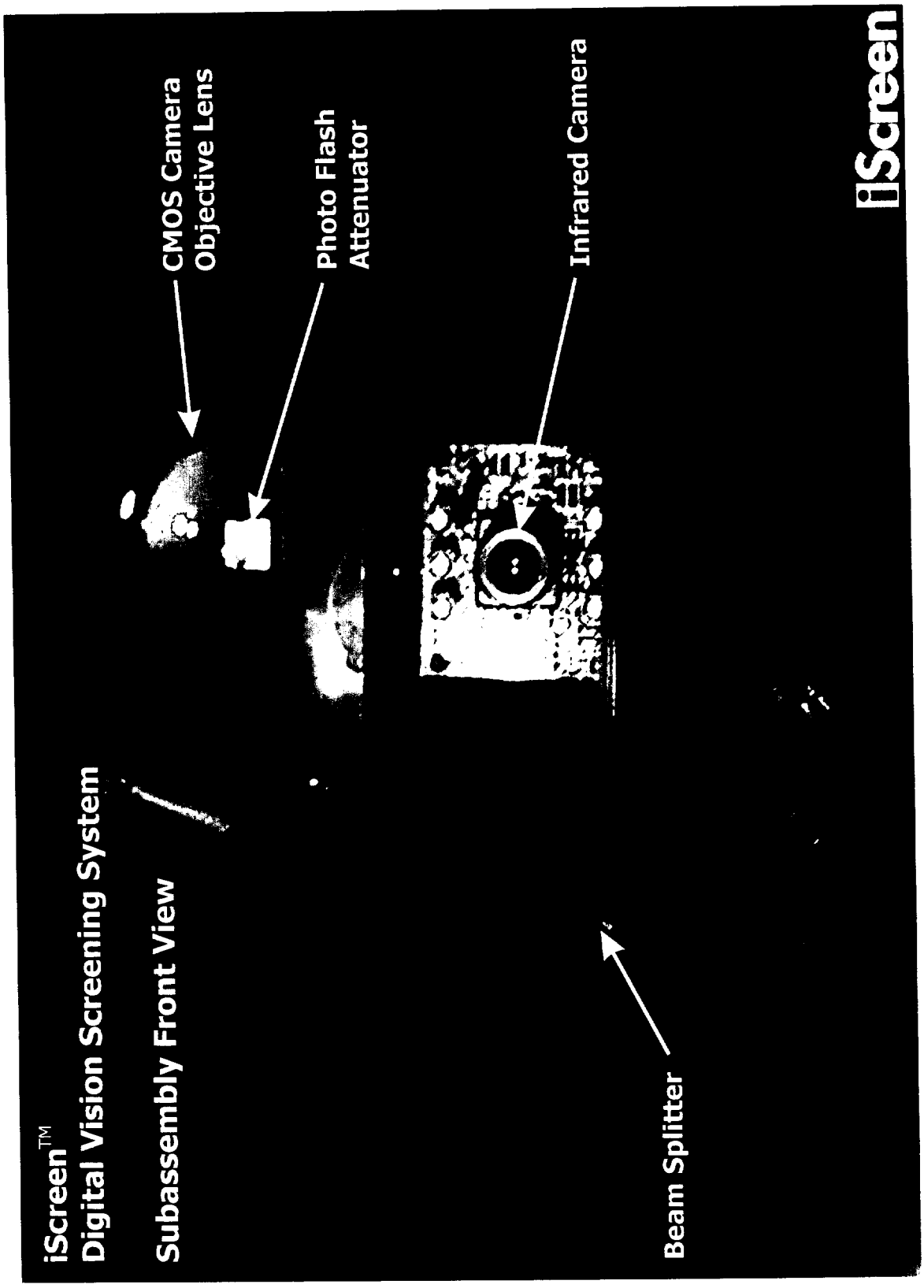


D3

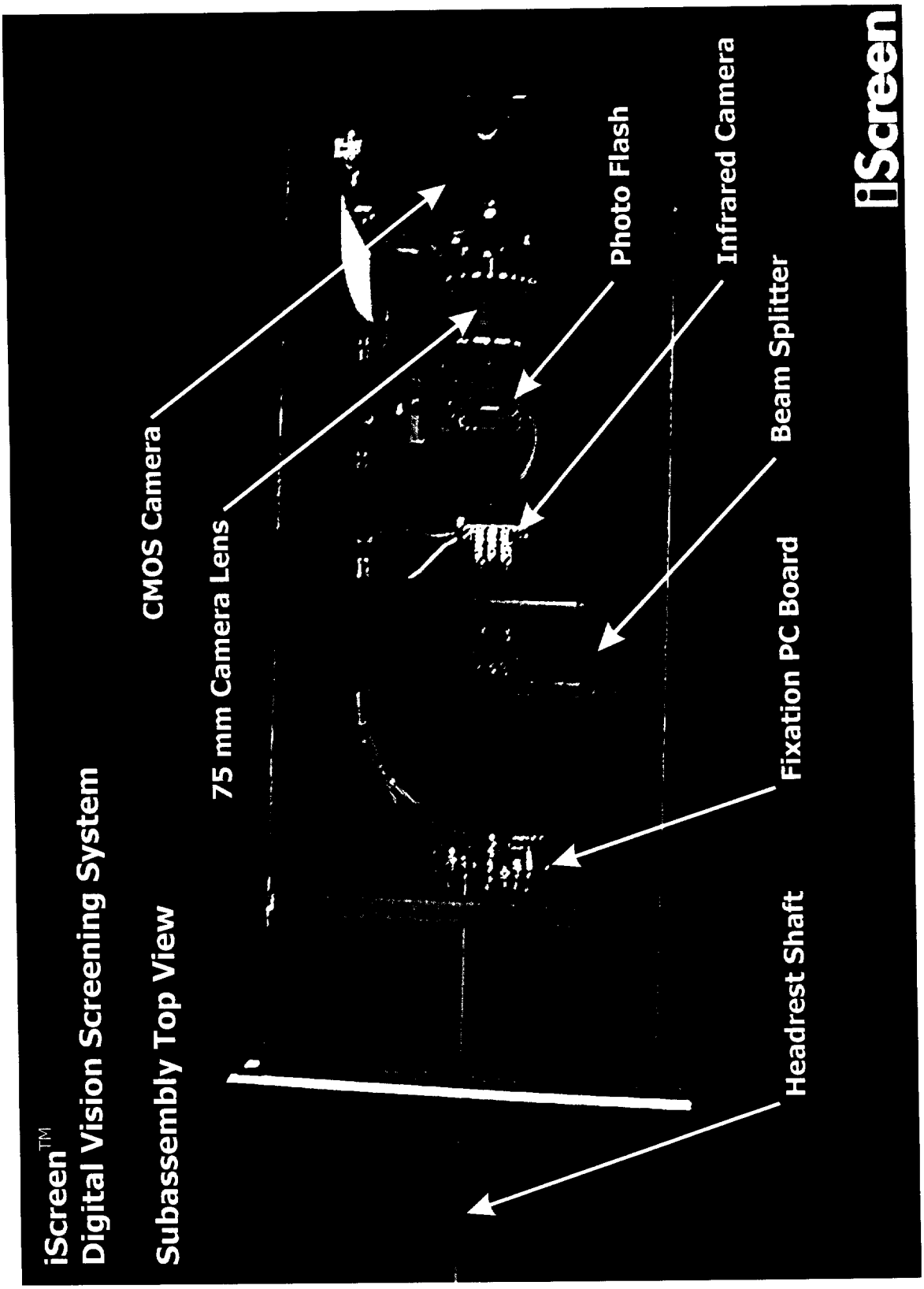




D5



D6



iScreen™
Digital Vision Screening System

Fixation and Power Distribution PC Board

Back View

Front View

iScreen

D8

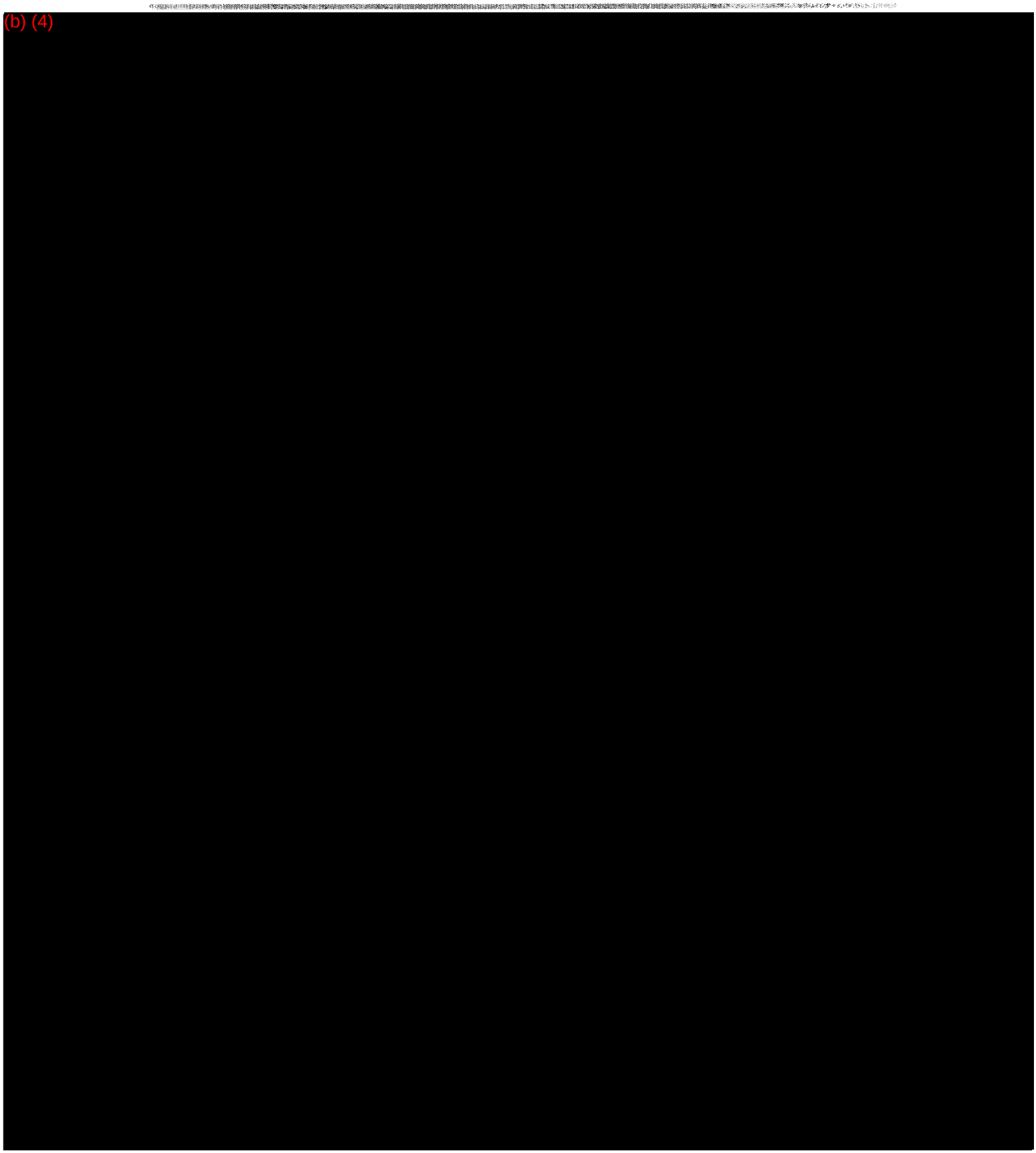
Appendix E

Engineering Drawings of the Device

iScreen™
Digital Vision Screening Technology

Engineering Specifications

(b) (4)



Components

(b) (4)

Headrest

(b) (4)

E2

(b) (4)

Digital Camera

(b) (4)

Photo Flash

(b) (4)

105

IR Camera

(b) (4)

[redacted]

Fixation Device

(b) (4)

[redacted]

Computer

(b) (4)

[redacted]

Table 1 – Design Specifications

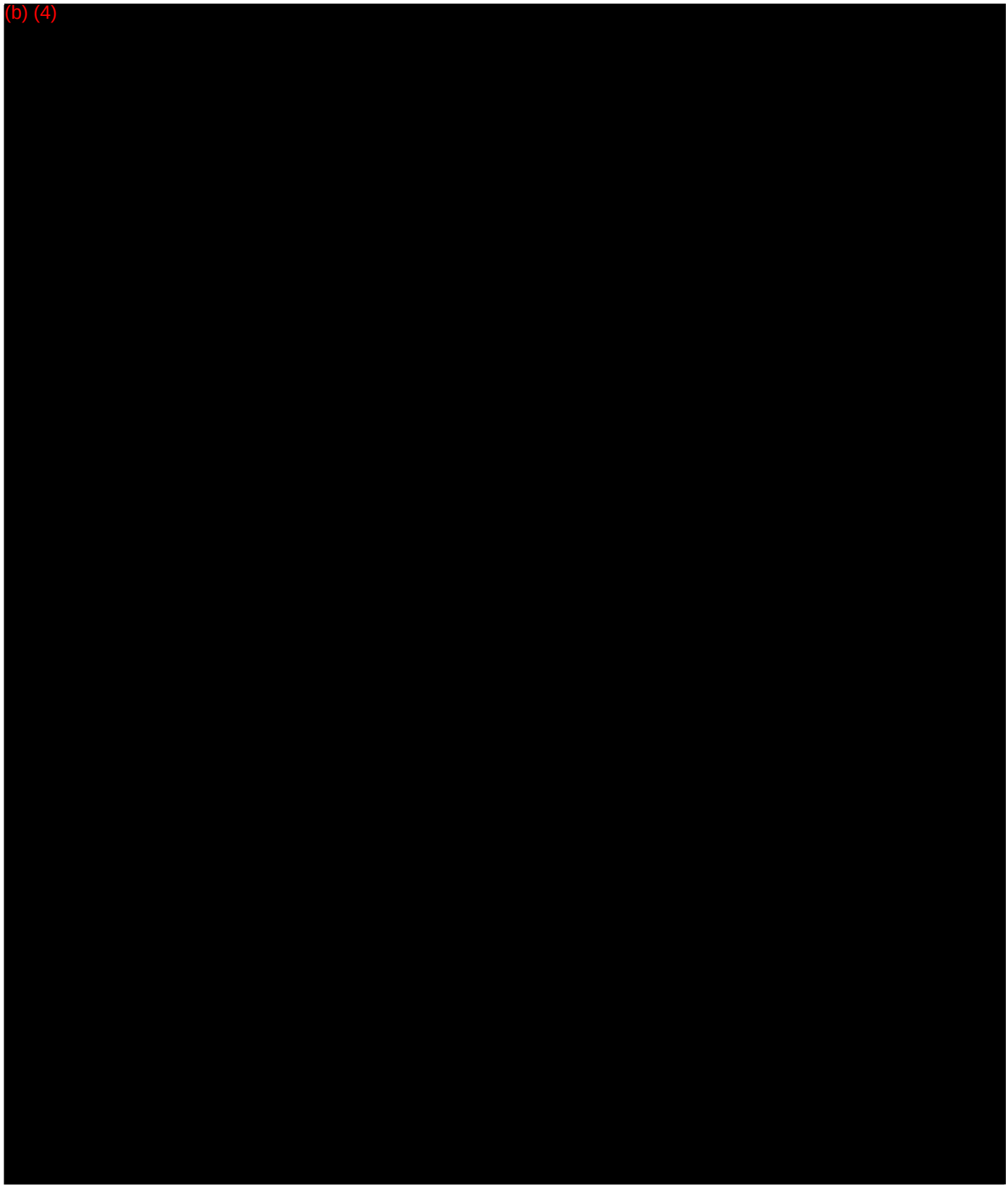
Component	Specification	Value	Notes
(b) (4)			

107

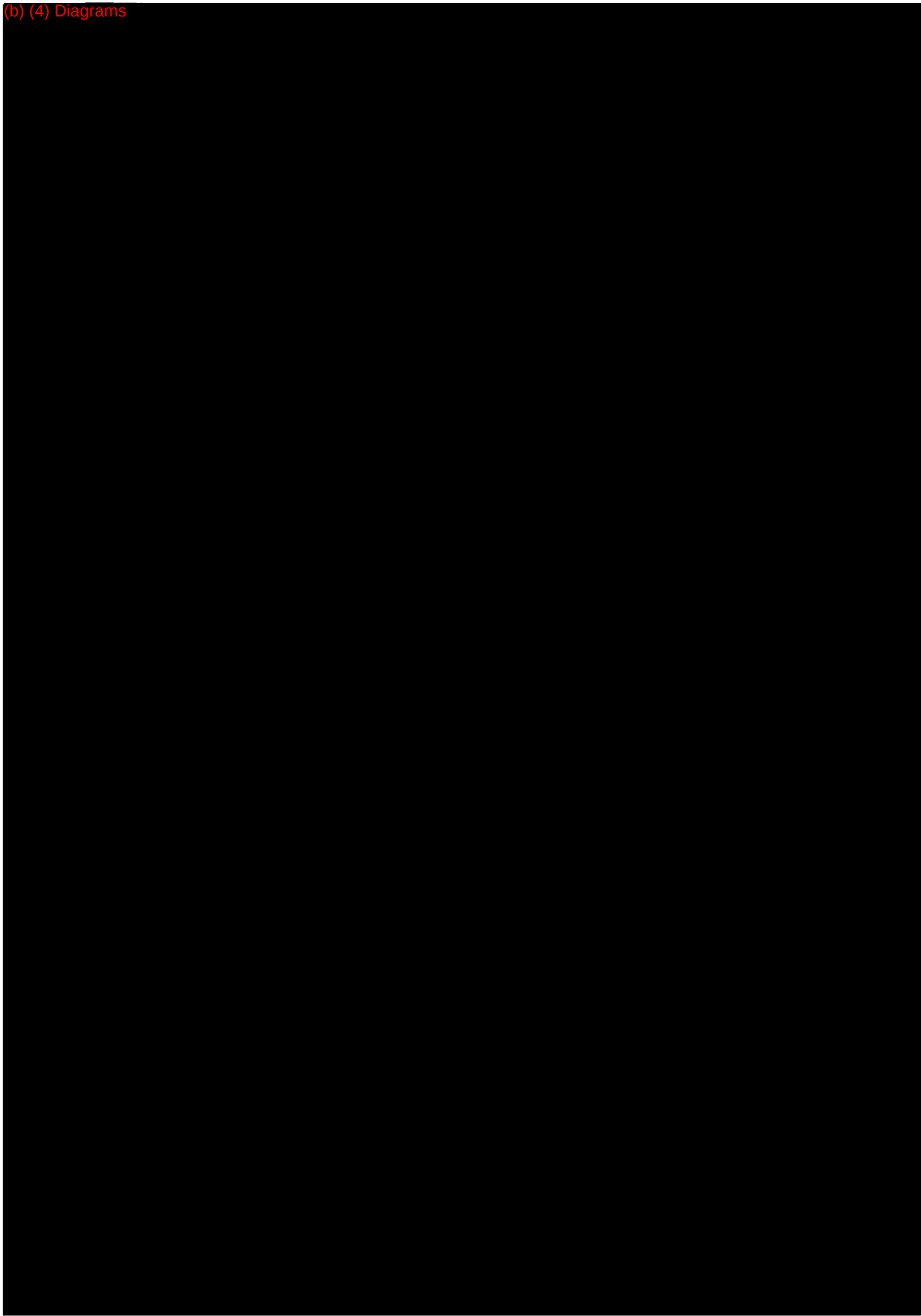
CONFIDENTIAL

ISCREEN SCHEMATIC
version 4 (10/10/99

(b) (4)



(b) (4) Diagrams



CONFIDENTIAL

(b) (4) Diagrams

[redacted]

CONFIDENTIAL

(b) (4) Diagrams

[redacted]

(b) (4) Diagrams

[redacted]

CONFIDENTIAL

(b) (4) Diagrams

[redacted]

(b) (4) Diagrams

(b) (4) Diagrams

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(b) (4) Diagrams

(b) (4) Diagrams

(b) (4) Diagrams

(b) (4) Diagrams

- CONFIDENTIAL -

(b) (4)

[redacted]

Schematic Drawing of iScreen Components and Critical Optical Path Dimensions

- CONFIDENTIAL -

[redacted]

Appendix F

Product Description and Comparison to Existing Marketed Devices

Screen
Digital Vision Screening Technology

I. Product Description

Principle of Operation

The iScreen Vision Screener belongs to a generic class of ophthalmic devices that utilize the technique of eccentric photorefraction to record the retinal reflex and ocular status of the eye. All of these instruments have similar primary components: 1) an illumination source, and 2) a recording device. These instruments project a beam of light onto the face and eyes of a patient. The recording device, typically a digital or film-based camera, records an image of the retinal reflex, sometimes called the "red reflex" or red eye phenomenon. This is the same phenomenon seen in family photographs when the flash source is close to the camera lens. The retinal reflex provides indications of the ability of the eye to focus light. The ocular status is also recorded in the same image since any degradation of the optics of the eye that would affect vision will also degrade the beam of light generated by the illumination source.

Components

The iScreen Vision Screener system is composed of two parts: 1) a camera unit that records the retinal reflex and ocular status, and 2) a computer that stores the data for later interpretation. The camera unit is similar to any ophthalmic camera, being comprised of a housing for components, a digital camera for recording the retinal reflex and ocular status, a flash system for generating light, a fixation device for attracting the patient's attention and an alignment camera that helps the user position the patient very accurately. The digital camera is becoming widely used in nearly all aspects of medical imaging. The light source used in this device is a standard photographic flash that is fitted with an attenuator that shapes the beam in to a line of light. The attenuating mask is a (b) (4) [redacted]

A fixation device is used to help the patient fixate directly into the camera lens. The process takes place in dim light so that the patient's pupils can dilate naturally. The iScreen software provides an easy interface for the user to enter patient information, and controls the digital and analog cameras in the screening device itself. The flash, fixation LED's and IR LED's ARE NOT SOFTWARE CONTROLLED, but are controlled by switching hardware. This design maximizes safety since all illumination sources are switched by the user or by hardware components and the software is used for data acquisition and storage. The photoflash is triggered by the digital camera using a (b) (4) [redacted]

(b) (4) [redacted]

Power Supply

The camera unit and computer are powered by a transformer that plugs into a standard 110 VAC wall outlet. The camera unit is supplied with 12 VDC and the computer with 14 VDC.

Typical Sequence

Before an image is acquired, the user enters appropriate patient information in fields provided by the computer software. When data entry is completed, the IR camera provides a video image on the screen. This allows the user to see the patient and to assist them into the proper position in a dimly lit room. When the patient is positioned, a digital image is acquired. Images are downloaded to the portable computer and stored in JPEG format. Corresponding patient data is embedded in the header of the JPEG file. The file can then be sent to a reading center for interpretation.

Comparison Chart

	MTI Photoscreener	Digital Retinoscopic Photometer	iScreen Vision Screener
Indications for Use	Detect and diagnose eye disease such as Amblyopia	Measure retinal reflex parameters and correlate measurements with typical value	(b) (4) [redacted]
Interpretation	Self trained image taker	Computer algorithm	
Intended Uses	1. Public health professionals 2. Mass screening groups 3. Pediatricians 4. Family medical doctors 5. Eye doctors	1. Public health professionals 2. Medical doctors, Optometrists, Opticians 3. Researchers in physiology and optics 4. Mass screening groups 5. Experimental animal investigations	
Conditions Detected	1. Myopia (Near-sightedness) 2. Hyperopia (Far-sightedness) 3. Strabismus (lazy eye) 4. Media opacity (eg. cataracts) 5. Anisometropia 6. Astigmatism	Does not detect disease, but only measures retinal reflex parameters and correlates measurements with typical values.	
Target Population	6 months to 10 years	6 months to 10 years	
Patient Requirements	Do not require dilation of eyes. Research indicates however, that accuracy in any photoscreener improves when patient's pupils are dilated.	Do not require dilation of eyes for young. May require dilation of eyes in older population. Research indicates however, that accuracy in any photoscreener improves when patient's pupils are dilated.	
Design	Compact portable device	Self-contained semi-portable device	

Reco

	MTI Photoscreener	Digital Retinoscopic Photometer	iScreen Vision Screener (b) (4)
Camera	Film - Polaroid	Digital - Charge Coupled Device (CCD)	[redacted]
Image Format	Polaroid grayscale (ISO 3200)	8-bit digital grayscale	
Development Time	Several minutes	Less than 10 seconds	
Patient Information Storage	Handwritten	Electronic	
Control System	Modified Polaroid Camera	Computer	
Electrical Requirements	Battery powered flash and camera.	Flash - 110 VAC by transformer to 12 VAC 20 VA; CCD = 110 VAC; Computer = 110 VAC; Printer = 110 VAC; Screen = 110 VAC	
Electrical Safety	Battery powered flash and camera	Unknown	
Thermal Requirements	N/A	N/A	
Chemical Requirements	N/A	N/A	
Radiation Requirements	N/A	N/A	

	MTI Photoscreener	Digital Retinoscopic Photometer	iScreen Vision Screener
Energy Delivered	Photo flash illumination is the only invasive quality. The intensity of the photo flash on this device is unknown.	Phtoo flash illumination is the only invasive quality. The intensity of the photo flash is 2.15 X 10^-6 W/cm^2.	(b) (4) [redacted]
Accuracy in Detection of Disease	Statistics vary according to report. Sensitivity 30% to 87%, specificity 60% to 89%, interobserver reliability (kappa) 0.3 to 0.5	Does not detect disease, but only measures retinal reflex parameters and correlates measurements with typical values	
Physical Safety	No known injuries in undetermined number of trials	No known injuries in 3,000 trials over five years	
Potential Areas of Failure to Perform	1. Old film 2. Inadequate batteries 3. Failure by patient to fixate on camera 4. Inaccurate/poorly trained interpretation of photoscreening image, resulting in False Positive or False Negative result	1. Incorrect computer measurements of characteristics of reflexes 2. Failure by patient to fixate on camera	
Consequences of Failure to Perform	Incorrect diagnosis resulting in under or over referral of patients	Incorrect measurement of retinal reflex	
Remedial Action of Failure to Perform	1. Repeat procedure 2. Standard Ophthalmic examination for diagnosis	Rerun algorithm of measurement of retinal reflex	

III. Discussion

The iScreen Vision Screener belongs to a generic class of ophthalmic devices that utilize the technique of eccentric photorefraction to record the retinal reflex and ocular status of the eye. This is the same technique is used by the MTI Photoscreener (K934880), Digital Retinoscopic Photometer (K951179), and other Ophthalmic Refractometer/Camera devices.

Both the MTI Photoscreener and iScreen Vision Screener rely on human interpretation of data to determine the results of a screening. Although the manufacturer of the Digital Retinoscopic Photometer does not claim differential diagnostic capability, the system employs computer algorithms to measure image parameters useful in assessing preliminary indications of vision problems.

The iScreen Vision Screener is composed of two parts: 1) a camera system that records the retinal reflex and ocular status, and 2) a computer that stores the data for later interpretation.

The camera system is similar to any ophthalmic camera, being comprised of a housing for components, a digital camera for recording the retinal reflex and ocular status, a flash system for generating light, a fixation device for attracting the patient's attention and an alignment camera that helps the user position the patient very accurately. The digital camera is becoming widely used in nearly all aspects of medical imaging. The light source used in this device is a standard photographic flash that is fitted with an attenuator that shapes the beam in to a line of light. The attenuating mask is a (b) (4)

(b) (4)

The Digital Retinoscopic Photometer and iScreen Vision Screener both use 110VAC as a power source. However, the iScreen Vision Screener employs an in-line transformer so that only 12VDC is supplied to the camera unit and 14VDC to the computer. The MTI Photoscreener is a battery-powered unit.

All eccentric photorefractors are marketed for similar purposes. Since a system employing this technique does not require verbal response from the patient, it can be used to screen patients of all ages for vision problems, and becomes particularly useful for preverbal children.

Unlike the MTI Photoscreener and the Digital Retinoscopic Photometer, which both record grayscale images, the iScreen Vision Screener records a color image using a Complimentary Metal-Oxide Semiconductor (CMOS) digital camera. The

MTI device uses a Polaroid™ camera and the Digital Retinoscopic Photometer uses a Charge Coupled Device (CCD) camera. Both the MTI Photoscreener and iScreen Vision Screener employ a fixation component, made up of blinking light emitting diodes (LED's) and an audible sound, to attract the patient's attention so that they fixate very close to the digital camera. The intensity of the fixation LED's is not enough to constrict a dilated pupil in most patients and is nearly negligible. Recall that pupil dilation is desirable since it increases accuracy. Red light (630 nm) from these LED's is reflected from a beam splitter so that only about 10% of the original intensity is reflected out of the enclosure. No more than 6 of the total 19 LED's are illuminated at one time.

The iScreen Vision Screener also uses (b) (4)

(b) (4)

[redacted]

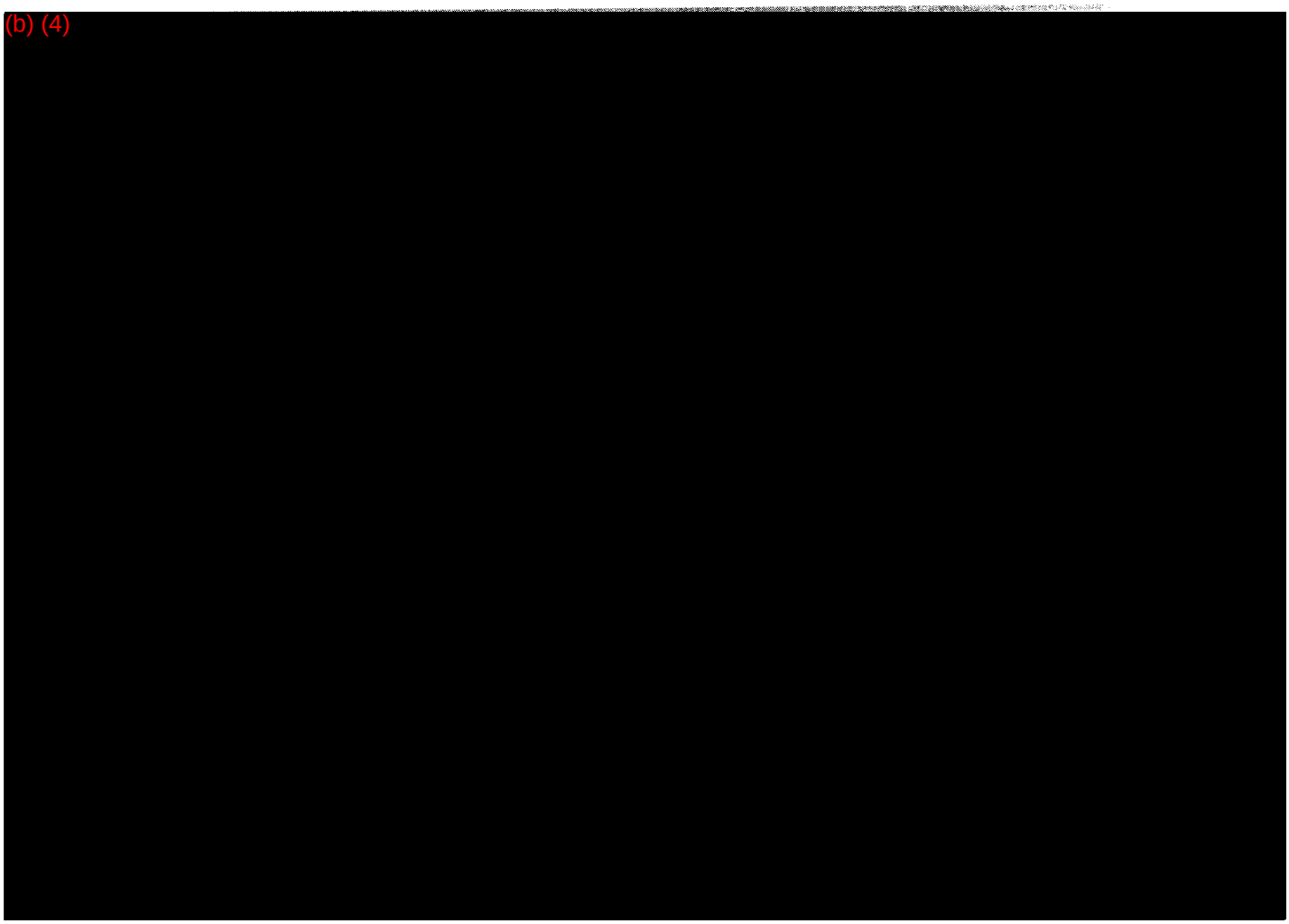
Appendix G

Biocompatibility Including Cytotoxicity and Illumination Intensity

Screen
Digital Vision Screening Technology

Biocompatibility

(b) (4)



[redacted]

Appendix H

Software Guidance Information

Screen
Digital Vision Screening Technology

Software Requirements Specification (SRS)

Overview

(b) (4)

[redacted]

Image Acquisition

Patient Information

(b) (4)

[redacted]

(b) (4)

[redacted]

Patient Alignment

(b) (4)

[redacted]

Review Image

(b) (4)

[redacted]

Transmit Images

(b) (4)

[redacted]

(b) (4)

[redacted]

Analysis Results

(b) (4)

[redacted]

Hardware Requirements

(b) (4)

[redacted]

Software and Interface Requirements

(b) (4)

[redacted]

(b) (4)

iScreen Software Flow Chart

(b) (4)

Validation, Verification and Testing (VV&T)

Overview

(b) (4)

[redacted]

Table 1 – Software Modules

Library	Module	Function
(b) (4)	[redacted]	

Testing

(b) (4)

[redacted]

(b) (4)

[redacted]

Results

(b) (4)

[redacted]

Table 2 – Software Changes

Development	Module	Modification
(b) (4)	[redacted]	

148

(b) (4)

[redacted]

Table 3 – Beta Test Error Codes, Number of Events and Response

ID	Description	No.	Response

(b) (4)

[redacted]

(b) (4)

150

FDA/CDRH IMAGING SYSTEM

Page Count Discrepancy Information

The page behind page 84 is marked 86.

Verifiers Initials CAB

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

1. Explain why not a device: N/A

2. Explain why not subject to 510(k): N/A

3. How does the new indication differ from the predicate device's indication: N/A

4. Explain why there is or is not a new effect or safety or effectiveness issue: N/A

5. Describe the new technological characteristics: N/A

6. Explain how new characteristics could or could not affect safety or effectiveness: N/A

7. Explain how descriptive characteristics are not precise enough: (See attached March 15, 2001 memorandum to the company.)

8. Explain new types of safety or effectiveness questions raised or why the questions are not new: N/A

9. Explain why existing scientific methods can not be used: N/A

10. Explain what performance data is needed: (See attached March 15, 2001 memorandum to the company.)

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: The performance data requested in FDA's March 15, 2001 memorandum was submitted in supplement 1 on May 7, 2001. The attached Review Addendum dated May 21, 2001 addresses how the performance data submitted were reviewed, found to be acceptable, and demonstrate that the device is substantially equivalent to the predicate device.

ATTACH ADDITIONAL SUPPORTING INFORMATION

(b) (4)

(Pat Cucenta) Heather 2wks

Add to documentation

510(k) Quality Review Program

Section 1 – Background Information

510(k) Number K010315 Date of Final Decision June 1, 2001

Final Decision SE Product Code HKI Panel Code Ophthalmic

Device Name iScreen Vision Screener

Class II Division DOED Branch DSDB

Submitter iScreen, LLC

Section 2 – Administrative Completeness

Was the Memorandum of Record Complete: Yes (No)

If "NO" Why Not? SE documentation questionnaire & explanation (review) Flowchart are inconsistent p12 (or p6 of review)

Section 3 – Decision
(Answer only those questions that were relevant to this 510(k))

Was the basis for the decision on each item adequate for the review/decision? Yes

(ANY NO ANSWER NEEDS AN EXPLANATION ATTACHED)

1.	Same indication statement:	(YES)	NO
2.	Does the difference alter the effect or raise new issues of safety or effectiveness :	YES	NO
3.	Same technological characteristics:	(YES)	NO
4.	Could the new characteristics affect the safety or effectiveness:	YES	NO
5.	Descriptive characteristics precise enough to ensure equivalence:	YES	(NO)*
6.	New types of safety and effectiveness questions:	YES	NO

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7. Accepted scientific methods exist: (YES)* NO

8. Performance data available: (YES)* NO

9. Data demonstrate equivalence: (YES)* NO

* reviews should provide specific answers to these Q's.

Section 4 – Summary of Findings

Quality Review Team: Jean Cooper
Pat Cricanti
Colin Pollard

Was there an adequate basis for the overall scientific decision? (YES) NO

If "NO" why not? (See Blue Book Memo K86-3)

Section 5 -- Follow-up

Issues Requiring Follow-up (please list):

Should complete the record re: SE documentation

Description of Issues:

Reviewed by: Cooper, Cricanti, Pollard 1/28/03

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