September 11, 2018</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Luke Ralston.

 *** This is a system-generated email notification ***

September 11, 2018

Apple Inc.
% Donna-Bea Tillman
Senior Consultant, Biologics Consulting Group
Biologics Consulting Group, Inc.
1555 King St, Suite 300
Alexandria, Virginia 22314

Re: DEN180044
Trade/Device Name: ECG App
Regulation Number: 21 CFR 870.2345
Regulation Name: Electrocardiograph software for over-the-counter use
Regulatory Class: Class II
Product Code: QDA
Dated: August 13, 2018
Received: August 14, 2018

Dear Donna-Bea Tillman:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the ECG App, an over-the-counter device under 21 CFR Part 801 Subpart C, with the following indications for use:

> The ECG app is a software-only mobile medical application intended for use with the Apple Watch to create, record, store, transfer, and display a single channel electrocardiogram (ECG) similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (AFib) or sinus rhythm on a classifiable waveform. The ECG app is not recommended for users with other known arrhythmias.
>
> The ECG app is intended for over-the-counter (OTC) use. The ECG data displayed by the ECG app is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from normal sinus rhythm and not intended to replace traditional methods of diagnosis or treatment.
>
> The ECG app is not intended for use by people under 22 years old.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ECG App, and substantially equivalent devices of this generic type, into Class II under the generic name electrocardiograph software for over-the-counter use.

FDA identifies this generic type of device as:

Electrocardiograph software for over-the-counter use. An electrocardiograph software device for over-the-counter use creates, analyzes, and displays electrocardiograph data, and can provide information for identifying cardiac arrhythmias. This device is not intended to provide a diagnosis.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On August 14, 2018, FDA received your De Novo requesting classification of the ECG App. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ECG App into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the ECG App can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	**Mitigation Measures**
Poor quality ECG signal resulting in failure to detect arrhythmia	Clinical performance testing Human factors testing Labeling
Misinterpretation and/or over-reliance on device output, leading to: • Failure to seek treatment despite acute symptoms • Discontinuing or modifying treatment for chronic heart condition	Human factors testing Labeling
False negative resulting in failure to identify arrhythmia and delay of further evaluation or treatment	Clinical performance testing Software verification, validation, and hazard analysis Non-clinical performance testing Labeling

False positive resulting in additional unnecessary medical procedures	Clinical performance testing Software verification, validation, and hazard analysis Non-clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the electrocardiograph software for over-the-counter use is subject to the following special controls:

1. Clinical performance testing under anticipated conditions of use must demonstrate the following:
    a. The ability to obtain an ECG of sufficient quality for display and analysis; and
    b. The performance characteristics of the detection algorithm as reported by sensitivity and either specificity or positive predictive value.

2. Software verification, validation, and hazard analysis must be performed. Documentation must include a characterization of the technical specifications of the software, including the detection algorithm and its inputs and outputs.

3. Non-clinical performance testing must validate detection algorithm performance using a previously adjudicated data set.

4. Human factors and usability testing must demonstrate the following:
    a. The user can correctly use the device based solely on reading the device labeling; and
    b. The user can correctly interpret the device output and understand when to seek medical care.

5. Labeling must include:
    a. Hardware platform and operating system requirements;
    b. Situations in which the device may not operate at an expected performance level;
    c. A summary of the clinical performance testing conducted with the device;
    d. A description of what the device measures and outputs to the user; and
    e. Guidance on interpretation of any results.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the electrocardiograph software for over-the-counter use they intend to market prior to marketing the device.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Luke Ralston at 301-796-6362.

Sincerely,

Angela C. Krueger -S

FDA

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health

DEN180044/A001

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 6, 2018

Re: DEN180044
(b) (4) App

Dear Linda Ricci:

I am submitting this amendment to request the following two adminstrative changes for DEN180044.

1. Change the name of the Submitter to Apple Inc.
2. Change the name of the device to "ECG App"

The full contact information for the Submitter/Applicant is:

Apple Inc.
One Apple Park Way
Cupertino, CA 95014

Please note that there is no change to the Primary Correspondent. It remains as:

Donna-Bea Tillman, Ph.D.
Senior Consultant
Biologics Consulting
1555 King St, Suite 300
Alexandria, VA 22314
410-531-6542
dtillman@biologicsconsulting.com

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This submission contains trade secret and confidential information. This information is exempt from public disclosure under the Freedom of Information Act, 5 U.S.C. § 552(b)(4), and may not be disclosed without the prior written authorization of Apple Inc. or its affiliates. Such disclosure is prohibited by the U.S. Criminal Code, 18 U.S.C. § 1905, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(j), and FDA regulations, 21 C.F.R. § 20.61(c). If FDA receives a

Biologics Consulting Group, Inc.
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request for this information and determines that disclosure may be appropriate, the Agency must comply with all provisions of 21 C.F.R. § 20.61(e), including by providing Apple Inc. with timely advance notice and a meaningful opportunity to object before making the disclosure, and a copy of any specific records the agency proposes to disclose.

If you have any questions about this request, do not hesitate to reach out to me or other members of the team.

Sincerely,

(b) (6)

Donna Bea Tillman, Ph.D
Senior Consultant, Biologics Consulting Group
(410) 531-6542
dtillman@biologicsconsulting.com

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Sincerely,

(b) (6) [redacted]

Donna Bea Tillman, Ph.D
Senior Consultant, Biologics Consulting Group
(410) 531-6542
dtillman@biologicsconsulting.com

DEN180044

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 13, 2018

Re: de novo Submission
Submitter: (b) (4)
Device Name: (b) App
Payment Identification Number: (b) (4)

Dear Luke Ralston:

I am submitting this de novo for the (b) (4) App, in accordance with the Modular Submission plan previously agreed to with FDA. This complete de novo contains all appendices as listed in the Table of Contents of the de novo.

The following documents were updated since Module 2:

Document Name	Updates
Software Requirements Specification (SRS) (Appendix I)	(b) (4)
Response to FDA Questions (Appendix T)	
Traceability Matrix (Appendix Q)	
(b) (4) Hazard Analysis (Appendix H)	
Verification (QA) Protocol (included in Appendix P)	

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BiologicsConsulting.com

All other documents submitted in Module 2 and via e-mail are identical to what is included in this submission.

Per FDA's request, we are providing in this de novo redlined versions of documents that were previously submitted during the review of (b) (4) where appropriate. Responses to FDA feedback during the review are (b) (4) are provided as Appendix T2.

The eCopy contains the following three volumes and content folders:

VOL_001 Cover Letter and Main Body
VOL_002 Appendices (Note: Appendix E is provided as a separate Volume)
VOL_003 Appendix E: (b) (4) Clinical Study Report & Appendices
VOL_004 References
STATISTICAL DATA – contains raw data and stats files for the clinical data
MISC – contains an Excel version of the Hazard Analysis, and clinical overview documents as discussed with FDA on August 9, along with the ECG waveforms as requested. Note that the waveforms with file names ending in "_REF.pdf" are for the reference ECG and files names ending in "_X.pdf" are for the subject device. The waveforms are provided in the following individual zip files:

- **Question 7** - Includes both reference and device strips for (b) (4) (b) (4)
- **Question 9** - Includes both reference and device strips for (b) (4) (b) (4)
- **Question 10** - Includes both reference and device strips for (b) (4) as reviewed
- **Question 12** - Includes both reference and device strips for (b) (4) (b) (4)

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If you have any questions or concerns, do not hesitate to reach out to me or other members of the team. We realize that the timeline for this project is very short, and we are very appreciative of FDA's willingness to work interactively with us.

Sincerely,

(b) (6)

Donna Bea Tillman, Ph.D
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U.S. Food and Drug Administration
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10903 New Hampshire Avenue
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August 13, 2018

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Payment Identification Number: (b) (4)

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Sincerely,

(b) (6)

Donna Bea Tillman, Ph.D
Senior Consultant, Biologics Consulting Group
(410) 531-6542
dtillman@biologicsconsulting.com

(b) (4)

(b) (4) Mobile Medical App

De Novo Classification Request

August 13, 2018

Submitter	(b) (4)
Primary Submission Correspondent	Donna-Bea Tillman, Ph.D. Senior Consultant Biologics Consulting 1555 King St, Suite 300 Alexandria, VA 22314 410-531-6542 dtillman@biologicsconsulting.com
Secondary Submission Correspondent	Calley Herzog Senior Consultant Biologics Consulting 1555 King St, Suite 300 Alexandria, VA 22314 720-883-3633 cherzog@biologicsconsulting.com

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1. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

See Appendix A for the completed cover sheet, FDA Form 3514.

2. COVER LETTER

The final, signed cover letter is provided as a separate PDF document on the eCopy of this submission.

3. INDICATIONS FOR USE

(b)(4) Draft

See Appendix B for the Indications for Use Statement, FDA Form 3881.

4. ADMINISTRATIVE INFORMATION

This *De Novo* submission is prepared in accordance with FDA Guidance Document "*De Novo* Classification Process (Evaluation of Automatic Class III Designation)" issued on October 30, 2017.

4.1. Device Name

Device Common Name: Mobile ECG Analysis Software

Device Trade / Proprietary Name: (b) (4) Mobile Medical App

4.2. Submitter and Contact Information

Submitter Name:	(b) (4)
Primary Submission Correspondent:	Donna-Bea Tillman, Ph.D. Senior Consultant Biologics Consulting 1555 King St, Suite 300 Alexandria, VA 22314 410-531-6542 dtillman@biologicsconsulting.com
Secondary Submission Correspondent:	Calley Herzog Senior Consultant Biologics Consulting 1555 King St, Suite 300 Alexandria, VA 22314 720-883-3633 cherzog@biologicsconsulting.com

4.3. Statements, Certifications, and Declarations of Conformity

N/A

5. REGULATORY HISTORY

5.1. Prior Submissions

There have been four pre-submissions about the (b) App:

(b) (4)

Summaries of each of these pre-submission meetings, along with the location of information responsive to FDA feedback, are provided below, and final meeting minutes are included in Appendix C.

(b) (4)

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

6. DEVICE OVERVIEW

6.1. Introduction

As is well recognized, Atrial Fibrillation (AF) is the most common serious cardiac arrhythmia, and when left untreated, is a leading cause of morbidity and mortality from stroke, heart failure, and myocardial infarction.[i,ii]

Early detection and treatment of patients with AF minimizes risk of sequelae of thromboembolism including >60% reduced risk of stroke.[iii,iv] However, many affected with AF are unaware they have this arrhythmia due to a number of factors including lack of symptoms, or experience only mild symptoms that they do not attribute to the disease.[v] As a result, asymptomatic patients are three times as likely to have sustained an ischemic stroke prior to diagnosis than those with symptoms.[vi,vii] These findings raise concerns and have prompted several variations of screening programs to identify patients with asymptomatic AF and prevent an embolic event.[viii,ix] While systematic and opportunistic screening programs have demonstrated increased rates of detection when compared to detection during routine clinical practice, such screening programs are not yet widely implemented.[x] Additionally, AF may be paroxysmal (PAF, or intermittent AF) and therefore missed by recording a single in-clinic ECG. This is especially true for those patients with intermittent symptoms. Holter devices are commonly used for ambulatory 24-hour ECG monitoring in at-risk patients, but have limited sensitivity for the detection of new AF.[xi]

The (b) (4) App allows individuals to take Lead I ECGs in their home, whenever convenient. This approach to obtaining ECG information is consistent with the shifting paradigm for how medical care is delivered in the US. HCPs are no longer the sole holders of medical knowledge as consumers become the primary authorities of their own health information.[xii] This is desirable for a number of reasons and is supported by a widely-referenced Institute of Medicine report that showed improving healthcare quality often depends on patients' involvement and engagement.[xiii]

This paradigm shift in healthcare is also supported by multiple federal legislative efforts. The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 and Centers for Medicare and Medicaid Services Incentive Program of 2014 for the Meaningful Use of Electronic Health Records both encourage the use of electronic health records through financial incentives for US hospitals. Related efforts by the U.S. Department of Health and Human Services (HHS) and other federal agencies, such as the Blue Button e-Health Program and endorsement of the Fast Healthcare Interoperability Resources (FHIR) standards, are currently underway to bolster individuals' access to their health records. As a result, approximately half of the US hospitals and 40 percent of physicians provide portals that allow patients to access their medical records and manage their health information.[xiv] Patients who have access to their medical records have reported a broader knowledge of their own health issues, which allows them to communicate more effectively with their physicians. These patients

are also more likely to initiate efforts to improve their health, which has been shown to lead to a decreased utilization of healthcare services.[xv,xvi,xvii]

6.2. Clinical Background

Atrial fibrillation (AF), the most common sustained serious cardiac arrhythmia with an estimated lifetime risk of one in four,[xviii,xix] accounts for 15% of the 700,000 strokes per year in the United States.[xx] In one study,[xxi] up to one-third of all strokes were attributable to AF. The prevalence of AF in the United States is estimated to be between 3 and 6 million,[xxii] and this number is expected to rise sharply to over 12 million by 2030[xxiii] due to an aging population and a rising age-adjusted incidence of AF. Oral anticoagulation (OAC) has been shown to substantially reduce the risk of AF associated stroke.[xxiv] However, 18% of AF-related strokes occur in patients with asymptomatic or subclinical AF that is newly-detected at the time of stroke.[xxv] Asymptomatic and subclinical AF have been associated with similar morbidity and mortality rates as symptomatic AF,[xxvi] and with similar rates of silent embolic events.[xxvii] Moreover, untreated AF substantially increases the risk of the development of heart failure and other cardiac complications. Therefore, earlier detection of asymptomatic or subclinical AF could reduce the total public-health burden of ischemic stroke, heart failure, and other AF-related sequelae with upstream therapies.

With an aging population in which AF prevalence is forecast to increase substantially,[xxviii] effective AF screening strategies may have important public health implications. These tools are not intended to replace the physician, but rather to augment the patient-provider relationship.

Guidelines for AF Screening

Contemporary international guidelines on primary prevention of AF-related stroke, and general guidelines on AF management, recommend opportunistic pulse detection (pulse palpation by trained health care personnel during routine health care contact) in patients ≥ 65 years of age.[xxix] In Europe, the newest 2016 guideline recommendations from the European Society of Cardiologists (ESC) allow for the replacement of pulse palpation with an ECG rhythm strip as an appropriate method of AF screening.[xxx]

While the U.S. Preventive Services Task Force currently does not recommend routine systematic screening for AF in general or high-risk populations, the recommendation[xxxi] was made due to a lack of evidence rather than evidence disproving the benefits of screening. The current evidence demonstrates screening with ECGs identifies more new cases of AF than usual care,[xxxii] and the use of handheld single-lead ECGs outside of a medical office improves the detection of AF compared to screening with an ECG in-office.[xxxiii] Because ECG confirmation is mandated by guidelines for the diagnosis of AF, handheld ECG devices have the advantage of providing a verifiable ECG trace and would therefore be the preferred screening tool.[xxxiv]

While mass screening has yet to be recommended in younger populations, younger patients with AF have higher mortality than matched controls without AF.[xxxv] Detection of AF in these populations is important as there is mounting evidence that demonstrates early management of the disease may prevent progression to permanent disease.[xxxvi] Furthermore, increasing evidence exists around lifestyle modification and its ability to prevent disease and the progression of disease.[xxxvii] Even though young, healthy patients who are found to have AF may not benefit from anticoagulation, these patients clinically must still be evaluated for the presence of other disease including structural heart disease, thyroid abnormalities, and substance abuse.[xxxviii] Devices such as the one described in this submission are needed to clarify the effectiveness of screening both in young and at-risk populations to better understand the natural history of the disease, prevention of disease, downstream health outcomes, cost-effectiveness, and impact on healthcare utilization.

Prevalence of Undiagnosed AF

Prior work indicates a high rate of undiagnosed AF in the general population. In a back calculating modeling study based on incidence of AF shortly following ischemic stroke in Medicare and commercial claims beneficiaries, there are an estimated 500,000 persons with undiagnosed AF in the United States, with an estimated incremental cost burden of $3.2 billion.[xxxix]

However, given the paroxysmal and asymptomatic nature of AF, brief intermittent screening strategies are highly insensitive and likely to only capture patients with high AF burden. This issue is highlighted by a study that demonstrated use of a handheld intermittent ECG monitor for 30 days improved detection of AF episodes compared to 24-48 hours of continuous ECG monitoring.[xl] Similarly, the investigation of prolonged ambulatory ECG screening (30 days) for AF after stroke, as compared to conventional 24-hour Holter monitors, detected 5-fold more AF (16.1% vs. 3.2%).[xli] With improvements in AF detection algorithms, long-term implantable cardiac monitors (ICM) are being increasingly used to screen for occult AF with recent studies in people equipped with ICMs demonstrating an average time to detection of AF of 123 days.[xlii] However, the benefits of long-term screening with this modality come with the downsides of an invasive procedure and high cost and are therefore not widely recommended. Given the limited wear-time of current ECG monitoring technologies, it is likely that a small but significant portion of the population remain undiagnosed despite normal screening mechanisms. This population would likely benefit from an easily available, non-invasive screening mechanism.

Wearable Health Technologies

Recently, there has been substantial uptake, both from consumers and patients**,** of wearable health technology such as wrist-worn devices incorporating multiple sensors. Such technologies can generate large amounts of real-time data on patient activity and heart rate variability, often through photoplethysmography (PPG)-based measurements of capillary blood volume. As

technologies advance and adoption increases, wearable health technologies will be able to deliver increasingly more complex information on patient health. To date, these data sources have largely been focused on monitoring activity and have shown some early benefits in the treatment of obesity and diabetes.[xliii,xliv] However, efficient utilization of wearable cardiac data to effect improvement in traditional patient outcomes has been limited. For decades, cardiac implanted electronic devices (e.g., pacemakers and implantable cardioverter defibrillators) have collected and transmitted real time patient data, ranging from measures of patient activity to life-threatening arrhythmia notifications. While these systems have been shown to improve clinical outcomes (e.g., time to clinical decision and mortality) and serve as proof of concept for wearable health technology based patient monitoring, they are not without risk. However, further investment and study are needed to develop and define wearable health technologies' health care applications.

6.3. Device Description

The (b) App comprises a pair of mobile medical apps—one on Apple Watch and the other on the iPhone—intended to record, store, transfer, and display Lead I ECG signals.

The (b) Apple Watch App (referred to as the "(b) Watch App" going forward) is intended to analyze Lead I ECG signals and detect the presence of atrial fibrillation (AF) and sinus rhythm in adults. The (b) iPhone App is included in the Health App, which allows users to store, manage, and share health and fitness data, and comes pre-installed on every iPhone.

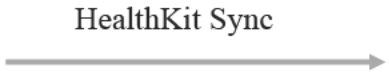
An image of the Health App and the Heart Portion of the Health App is provided in Figure 6-1.

Figure 6-1 Health App and the Heart Portion within the Health App

We consider the (b) iPhone App to be the (b) User Interface (UI) Framework as well as the information included in the ECG portion of the Health App. The (b) UI Framework contains the on-boarding and educational materials that a user must review prior to taking an ECG reading on the (b) Watch App. After a user completes a session on the (b) Watch App, the results from that session are displayed in the ECG portion of the Health App. Please see Appendix J for the Software Design Specifications (SDS) which provides details on this functionality.

Figure 6-2 shows the functionality of each of the (b) Watch App and (b) iPhone App, and the syncing of the session result between the two at the end of a session.

Figure 6-2 A Summary of the Functionalities of (b) Watch App and (b) iPhone App



[redacted]

(b) Watch App

The (b) Watch App is an on-demand ECG analysis app that runs on the Apple Watch. The Apple Watch (b) (4) will include integrated electrical sensors (electrodes). One electrode is located on the back of the Apple Watch and the other one is location on the digital crown of the Apple Watch (See Figure 6-3).

Figure 6-3 Digital Crown of the Apple Watch-Schematic Drawing

The (b) Watch App instructs the user to take an ECG measurement by holding their finger on the digital crown of the Watch. The electrical sensors (part of platform hardware) will sense and acquire Lead I ECG signals, and the Watch App will display a visual representation of the ECG waveform to provide information regarding signal quality during the session. The waveform displayed during the session is not intended for clinical purposes. The session will last for 30 seconds. (b) (4)

An image of a user taking an ECG measurement is provided in Figure 6-4.

Figure 6-4 Taking an ECG Measurement

(b) (4)

The (b) Watch App will classify ECG signals into one of the following categories described in Table 6-1:

Table 6-1 (b) Rhythm Classifications

#	UI Output	Definition	Algorithm Output
1	**Title: Sinus Rhythm** Description: This ECG does not show signs of Atrial Fibrillation.	Regular rhythm with a HR between 50-100 bpm and less than 4 ectopic beats	regular_rhythm
2	**Title: Atrial Fibrillation** Description: This ECG shows signs of AFib. If this is an unexpected result, you should talk to your doctor.	AF with a HR between 50-100 bpm	Afib
		AF with a HR between 101-120 bpm	Afib_HighHR
3	**Title: Inconclusive** Description: Your ECG is inconclusive and will be saved. If you repeatedly get this result or you're not feeling well, you should talk to your doctor.	Regular rhythm with a HR greater than 100 bpm	Unclassified_SinusTach
		HR over 120	Unclassified_HighHR
		HR under 50	Unclassified_LowHR
		"Other" Rhythms: Rhythms other than AF or regular rhythm)	Unclassified_other
4	**Title: Inconclusive** Description: Your ECG is inconclusive due to a poor reading but will be saved.	Poor Recording (e.g., noise, artifact, or poor signal quality)	Unreadable

Once the (b) Watch App analyzes the ECG data, the Watch App displays the rhythm classification, average heart rate, a description of the rhythm classification to the user on their Apple Watch. The session result is saved in Watch HealthKit and is then retrieved and stored in HealthKit on the paired iPhone.

Once the user sees the result of a given session on the Apple Watch, the user will have the opportunity to pick from the following list of symptoms, which will be saved as part of the session result in Watch HealthKit:

- Rapid, pounding, or fluttering heartbeat
- Skipped heartbeat
- Fatigue
- Shortness of breath
- Chest tightness or pain
- Fainting
- Dizziness
- Other
- None

(b) iPhone App

The (b) iPhone App is designed to work in combination with the (b) Watch App. The (b) iPhone App provides the user with on-boarding and access to educational material. In addition, the (b) iPhone App retrieves the session result (ECG waveform, average heart rate, rhythm classification) and any selected symptoms from HealthKit on the iPhone, displays these results, and allows users to share session results with their physician. There is no real time display of ECG on the (b) iPhone App.

For purposes of this submission, the "(b) App" refers to the (b) Apple Watch App and (b) iPhone App collectively. Examples of rhythm classification displays in (b) Watch App and (b) iPhone App are provided in Figure 6-5 and Figure 6-6, respectively.

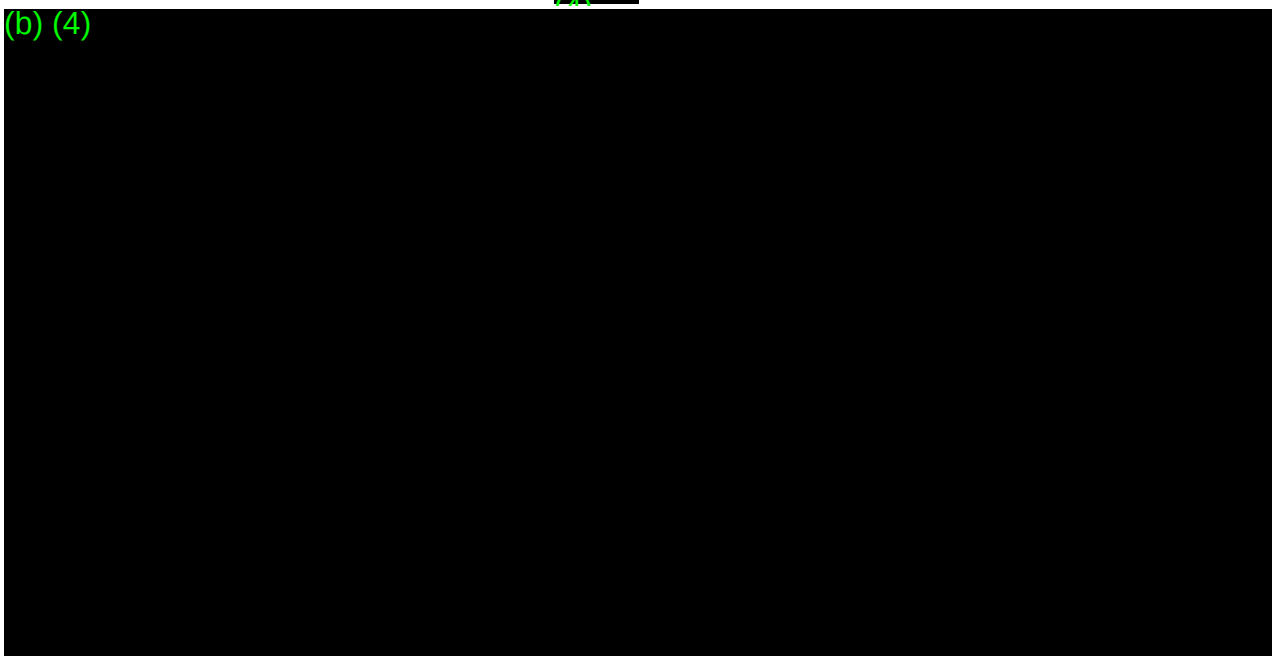
A complete copy of the wireframes is provided in Appendix D.

Figure 6-5 An Example of a Rhythm Classification Display in (b) Watch App

Figure 6-6 An Example of a Rhythm Classification Display in the (b) iPhone App

6.4. Principles of Operation: (b) (4) Algorithm (Waveform Processor)

(b) (4)



6.5. Proposed Conditions of Use

(b) (4)

6.6. Device Components

The (b) (4) App comprises two apps: the (b) (4) Watch App and the (b) (4) iPhone App. The (b) (4) Watch App analyzes the Lead I ECG signals and detects the presence of AF and sinus rhythm. The (b) (4) iPhone App provides the user with on-boarding and access to educational material. In addition, the (b) (4) iPhone App retrieves the session result (ECG waveform, average heart rate, rhythm classification) and chosen symptoms from HealthKit on the iPhone, displays these results, and allows users to share session results with their physician if desired.

6.7. System Accessories

There are no system accessories. The (b) Apps require the Apple iPhone (5s or later) with iOS version 12.0 or later and Apple Watch (Series 4 or later) with watchOS version 5.0 or later general purpose computing platforms.

6.8. Materials

(b) is a software-only device; therefore, this section is not applicable.

6.9. Sterilization & Shelf Life

(b) is a software-only device; therefore, this section is not applicable.

6.10. Packaging

(b) is a software-only device; therefore, this section is not applicable.

6.11. Alternative Practices and Procedures

FDA has cleared many ECG products, but none for OTC use. Recently, FDA cleared the AliveCor KardiaBand, (K171816), the software component of which is the product most similar to the (b) App. The KardiaBand is cleared for prescription and OTC use, and does not show the waveform to the user on the Apple Watch until a clinician has had an opportunity to review the first reading. Once the first reading has been reviewed, the user is able to take an ECG at their convenience, see the waveform on the Apple Watch, and review the results in an iPhone app, similar to the (b) App experience. Key differences between KardiaBand and the (b) App are that the (b) App will be OTC only, and will not require an initial physician consult prior to use.

There are other types of ECG products that have also been cleared by FDA, for example, implantable cardiac monitors, Holter monitors, and ECG patches. Implantable cardiac monitors carry a significantly greater risk than the (b) App, and Holter monitors and ECG patches can only be worn for a short period of time, potentially making it difficult to identify AF during the time of device wear. There are also ECG devices intended for use in a clinical setting, e.g., 12-lead ECGs and continuous cardiac telemetry monitoring. Similar to Holter monitors and ECG patches, 12-lead ECGs capture only a moment in time, again making it difficult to identify AF during the time of wear.

The data acquired and analyzed by these devices have traditionally been reported directly to a clinician. It is then the clinician's responsibility to pass this information onto the consumer. In many cases, this information is passed to the consumer verbally or handed to the consumer on a

physical printout making it difficult for the consumer to easily pass this information onto caregivers and/or other healthcare providers.

As healthcare moves towards improving transparency in pricing and quality, it is essential that medical data such as ECGs become more transparent as well. This transparency will ultimately facilitate consumer understanding of their own health issues, allowing them to communicate more effectively with their physicians and leading to improved engagement.

Thus, although ECG devices are not novel, the intended use of the (b) App is unique in that it is intended for OTC use only. Apple believes that the availability of an OTC ECG product will empower users to take control of their health data in a manner not facilitated by other currently marketed ECG products, and will enable users to engage in conversations with their physicians with ease in a novel and new way.

7. PROPOSED DEVICE CLASSIFICATION

7.1. Predicate Review

7.1.1. Classification Searches

Apple searched the FDA Product Classification and 510(k) databases to determine if FDA has previously cleared any over-the-counter ECG devices. The following table lists the product codes and classification regulations that were considered.

Product Code	Classification Regulation
DXH (Transmitters and Receivers, Electrocardiograph, Telephone)	870.2920 Telephone electrocardiograph transmitter and receiver
MHX (Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms))	870.1025 Arrhythmia detector and alarm
DSI (Detector and Alarm, Arrhythmia)	870.1025 Arrhythmia detector and alarm
DPS (Electrocardiograph)	870.2340 Electrocardiograph

7.1.2. Similar Devices

As noted above in section 6.11, there are a number of FDA-cleared ECG products. The devices with the most similar indications for use are the AliveCor Kardia (K142743) and KardiaBand (K171816), but those devices require a remote clinician to review the first waveform before unlocking for on-demand use. As FDA has noted in prior discussions (see meeting minutes from (b) (4) FDA considers previously-cleared ECG products, including the AliveCor devices, to be prescription devices, and for that reason determined those products not to be appropriate predicate devices.

7.1.3. Why (b) App is Different

As noted above, FDA previously indicated that there is no appropriate predicate device for the (b) App, since the (b) App is intended only for OTC use, and therefore the de novo classification process is appropriate.

7.2. Classification Recommendation

Apple proposes that the (b) App be classified as a Class II device, Mobile ECG Analysis Software, subject to general and special controls. Pursuant to section 515(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(a)(1)(C)), Class III devices are those that are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or that presents a potential unreasonable risk of illness or injury. The (b) App does not meet this definition of a Class III device. It is not purported or represented to be for a use in supporting or sustaining human life, it is not for a use which is of substantial importance in preventing impairment of human health, and it does not present a potential unreasonable risk of illness or injury. Rather, it is intended to allow individuals to acquire and store their ECG waveform, and share it with their clinician, if desired. Users will also be able to better understand their heart rates and heart rhythms in relation to their overall health, thus providing users more control over and insight into their personal health information. Given this intended use of the device, it does not meet the definition for a Class III device. The potential risks of the (b) App are also comparable to those of other OTC device types that FDA has classified as Class II, including non-invasive blood pressure devices and pregnancy test kits, and the (b) App presents significantly less risk than other OTC Class II devices, such as blood glucose meters.

Apple has proposed below the special controls that it believes are adequate, in conjunction with the general controls set forth in the FD&C Act, to demonstrate reasonable assurance of safety and effectiveness of the device type Mobile ECG Analysis Software.

7.3. Proposed Special Controls

Apple proposes that, in combination with general controls, the Mobile ECG Analysis Software should be subject to the following special controls:

(b) (4)

(b) (4)

8. SOFTWARE DOCUMENTATION

8.1. Statement of Level of Concern

The software level of concern for the (b) App is **Moderate**.

This determination was reached by a careful review of the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff" (5/11/2005). The following list of questions and answers gives a summary of that decision making process:

Questions for Major Level of Concern

1. Does the Software Device qualify as Blood Establishment Computer Software?

   No

2. Is the Software Device intended to be used in combination with a drug or biologic?

   No

3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?

   No

4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:

   a. Does the Software Device control a life supporting or life sustaining function?

      No

   b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?

      No

   c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?

No

d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?

No

e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?

No

Questions for Moderate Level of Concern

1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?

   No

2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?

   No

3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

   Yes. A malfunction or latent design flaw in the (b) App could lead to a delay in delivery of appropriate medical care. For example, if the device incorrectly classifies Atrial Fibrillation as a Sinus Rhythm, the user may not have a reason to seek appropriate medical care (particularly if they are asymptomatic). However, the user should not be relying on the (b) App as a diagnostic, and if they are feeling symptoms or feel that they are experiencing an emergency, the (b) App encourages them to seek medical care.

Based on the answers to question #3 above, the software level of concern for the (b) App is **Moderate**.

8.2. Software Description

As this is a standalone software device, the device description and algorithm description provided above (Sections 6.3 and 6.4) describe the device features and intended operational environment. The following information is provided according to the software guidance:

- Programming language: C, C++, Objective C
- Hardware platform: Apple Watch Series 4 or later, iPhone 5s or later
- Operating system (if applicable): watchOS 5.0, iOS 12.0
- Use of Off-the-Shelf software: See Appendix N

8.3. Device Hazard Analysis

The device hazard analysis was provided in Module 1 and Module 2. Apple has made additional changes since Module 2 to the hazard analysis to be more precise and make clarifications. Please see redlined and clean versions in Appendix H1 and H, respectively.

A usability risk analysis was also performed to address the foreseeable use errors. A copy of the usability risk analysis is provided in the HFE report (Appendix S).

8.4. Software Requirements Specification (SRS)

The Software Requirements Specification was provided in Module 1 and 2. Minor changes were made (b) (4) [redacted] No changes were made to the functionality of the App.

8.5. Architecture Design Chart

The system architecture specification, including the design chart was provided as Appendix G in Module 2. No changes have been made to this document.

8.6. Software Design Specification (SDS)

The Software Design Specification was provided as Appendix J in Module 2. No changes were made to this document since that submission.

8.7. Traceability Analysis

The Traceability Analysis, without verification results, was included Module 2. Traceability was updated (b) (4) [redacted]. Refer to Appendix Q for the Traceability Analysis Matrix.

8.8. Software Development Environment Description

Apple has established procedures for software design and development, configuration management, and maintenance plans.

(b) (4) [redacted]

(b) (4)

8.9. Verification and Validation Documentation

This section describes end-to-end design verification testing for the (b) App to show that the requirements outlined in the SRS in Appendix I are met. The results of this testing are included in Appendix P (b) (4)

There are two subsets of design verification testing (b) (4)

(b) (4)

8.10. Revision Level History

The revision level history is provided below (Table: Revision Level History). (b) (4)

Table: Revision Level History

Test	Algorithm Version	App (UI) Version
(b) (4)		

Table: Bug Fixes/Algorithm Changes (b) (4)

Bugs / Change #	Change Type	Change Summary
(b) (4)		

Table: Bug Fixes/Algorithm Changes (b) (4)

Bugs / Change #	Change Type	Change Summary
(b) (4)		

Table: Bug Fixes/Algorithm Changes (b) (4)

Bugs / Change #	Change Type	Change Summary
(b) (4)		

Table: Bug Fixes/Algorithm Changes (b) (4)

Bugs / Change #	Change Type	Change Summary
(b) (4)		

8.11. Unresolved Anomalies (Bugs or Defects)

Unresolved anomalies are provided below.

Bug#	Description	SRS Impacted	Status	Impact on S&E
(b) (4)				

Bug#	Description	SRS Impacted	Status	Impact on S&E
(b) (4)				

8.12. Cybersecurity

Cybersecurity documentation in accordance with FDA's guidance document Content of Premarket Submissions for Management of Cybersecurity in Medical Devices is provided in Appendix M. No changes were made since Module 2.

8.13. Off-the-Shelf Software

Basic Information for Off the Shelf software in accordance with FDA's guidance document on Off-the-Shelf Software Use in Medical Devices is provided in Appendix N. No changes were made since Module 2.

9. SUPPORTING PROTOCOLS AND/OR DATA

9.1. Platform Requirements

9.1.1. Safety

All Apple Watch products are evaluated to demonstrate compliance with applicable thermal safety, battery safety, and RF and EMC for emission and immunity guidelines. A summary of the applicable guidelines and associated testing is provided below.

9.1.1.1. Thermal Safety Testing

To prevent a thermal hazardous situation when a user makes contact with the external surface of the platform, Apple requires that the Apple Watch series 4 (final finished product for product release) is tested and shown to be in compliance with applicable thermal safety requirements of IEC 60950-1, *"Information Technology Equipment – Safety Part 1: General Requirements."* and IEC 62368-1, *"Audio/video, information and communication technology equipment - Part 1: Safety requirements"* before the product is released. The requirements of IEC 62368-1 are similar to the requirements from IEC 60601-1 "Medical electrical equipment –Part 1: General requirements for basic safety and essential performance". The thermal safety (external surface) requirements specified for the Apple Watch are summarized in Table 9-1.

Table 9-1 Thermal Safety Requirements (External Surface)

Usage Mode	Material Type	Maximum Temperature During Normal Use (°C)		
		*IEC 60950-1 Requirement	**IEC 62368-1 Requirement	*IEC 60601-1 Requirement
Discharge mode (devices worn on the body in direct contact with skin)	Metal	55	43	43
	Glass	65	43	43
	Plastic	75	43	43
Discharge mode (surfaces likely to be touched while in use)	Metal	55	48	48
	Glass	65	48	48
	Plastic	75	48	48
Charging mode (Inductive charger and restore connector)	Metal	60	51	51
	Glass	70	56	56
	Plastic	85	60	60

*Surface temperature limits for all operating ambient temperatures; Apple defines the maximum operating ambient temperature

**Surface temperature limits while tested in a 25ºC ambient

9.1.1.2. Leakage Current

As a general purpose computing platform, the Apple Watch is not required to be tested or show compliance for leakage current in accordance to IEC 60950-1 due to the classification of the equipment in the standard. However, Apple has elected to perform leakage current testing before product release in accordance to IEC 60601-1 to ensure the Watch will not pose a safety hazard to the user. The leakage current is measured in patient leakage condition (patient connection to ground) and patient auxiliary condition (patient connection to all other patient connections). The testing requirements for leakage current specified for the Apple Watch are summarized in Table 9-2.

Apple will test Apple Watch Series 4 (final finished product for product release) for leakage current per the following IEC60601-1 requirements and test methods. Apple will not release Watch Series 4 until the testing demonstrates the requirements are met.

Table 9-2 Applicable Leakage Current Requirements from IEC 60601-1

Current	Description Per IEC 60601-1	IEC 60601-1 Reference	Normal Condition	Single Fault condition
			Current in uA	
Leakage	Patient connection to ground	8.7.4.7 (a)	10	50
Auxiliary	Patient connection to all other patient connections	8.7.4.8	10	50

9.1.1.3. RF and EMC Testing for Emission and Immunity

Apple also requires the Apple Watch to be tested and shown to comply with US FCC Part 15 Rules for radio frequency devices and EN 301 489-17 V 3.2.0 "Electromagnetic Compatibility Standard for Radio Equipment – Part 17: Specific conditions for Broadband Data Transmission Systems." To date, all released Apple Watch products have met the requirements of not emitting electromagnetic disturbance that could affect other radio frequency services and essential performance of other equipment. The Apple Watch has been shown to maintain adequate immunity to electromagnetic disturbance during operation.

FCC ID is posted on the regulatory page under settings in each product. Declarations of Conformity for EN 301 489-17 V 3.2.0 is posted on Apple website at https://www.apple.com/euro/compliance/.

9.1.1.4. Battery

To address the concerns of fire hazards and to prevent the product from being the source of combustion, the batteries from both the released Apple Watch and iPhone products are tested and certified to the standards in Table 9-3.

Apple will conduct battery testing for Apple Watch Series 4 (final finished product for product release) per standards listed in Table 9-3. Apple will not release Watch Series 4 until the certification processes have been completed successfully.

Table 9-3 Battery Certifications

Battery Type	Certification

Cell	• IEC 62133 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications • UL1642 Standard for Lithium Batteries • CTIA Certificate - IEEE 1725 Requirements for Rechargeable Batteries for Cellular Telephones
Pack (Cell and battery management unit)	• IEC 60950-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance • IEC 62133 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications • UL 2054 Standard for Household and Commercial Batteries • CTIA Certificate - IEEE 1725 Requirements for Rechargeable Batteries for Cellular Telephones

9.2. Platform Performance

Additionally, a set of specific requirements has been defined to support the (b) ECG measurement quality. Detailed platform requirements have been updated and provided in the Software Requirements Specifications document. See Appendix I.

As a part of both the development of Apple's products, and the on-going product assembly process, there are several ways in which the company ensures products meet their design requirements, and customer expectations.

This summary highlights the relevant testing that occurs as a part of the engineering sign off, and the manufacture of each individual product.

9.2.1. Platform Production Testing and Engineering Sign-Off

(b) (4)

Table 9-4 Critical Platform Requirements

SRS #	Testing Coverage	Platform Requirement
(b) (4)		

(b) (4)

Table 9-5 Operational Conditions

SRS #	Test Coverage	Operational Conditions
(b) (4)		

Finally, Table 9-6 below captures the remaining Platform requirements, (b) (4)

Table 9-6 Summary of QA testing

SRS#	Test Reference	Platform Requirements
(b) (4)		

(b) (4)

9.2.2. On-Going Production

(b) (4)

9.3. Performance Testing - (b) App

Apple is submitting the following testing to support the performance of the (b) App (iPhone App and Watch App).

- Algorithm development and engineering testing (Section 9.2.1, below)
- ECG measurement quality per IEC 60601-2-47. (b) (4) Appendix K)
- Software verification. High-level plan included in Section 8.9; results included in Appendix P.
- Human Factors Testing (Section 9.3.3, below)
- Clinical Validation testing (Section 9.3.5, below)
- Database Testing per EC-57 on MIT-BIH and AHA (Appendix V)

9.3.1. Algorithm Development

Apple conducts rigorous data collection and engineering testing in order to develop and tune its algorithms. During initial development of the (b) algorithm (described in the Algorithm Description above), Apple conducted a variety of engineering studies to collect data used for core algorithm development.

(b) (4)

[redacted]

9.3.1.1. (b) Algorithm Development

(b) (4)

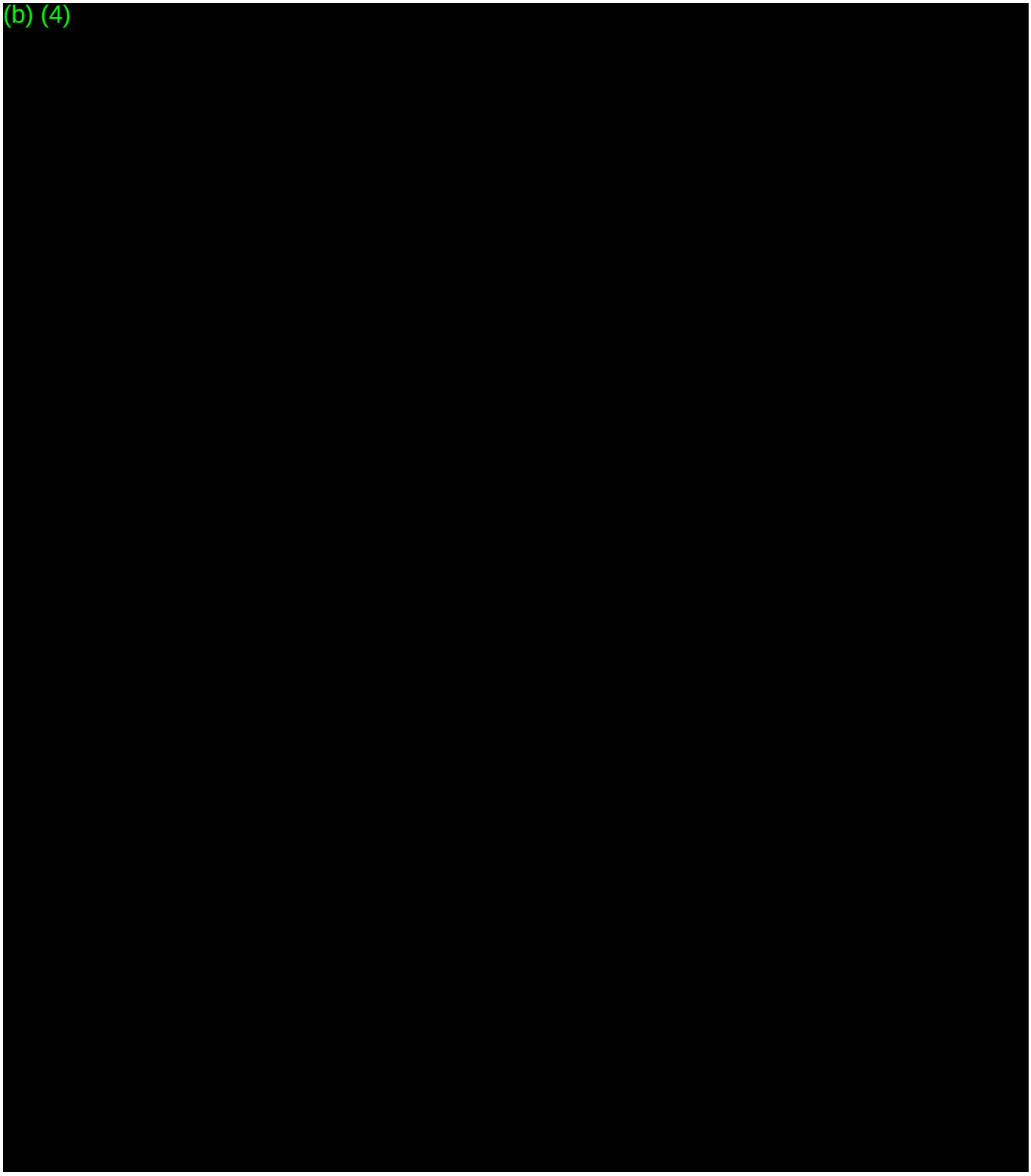
[redacted]

Table 9-7 Overview of Algorithm Development Studies

Study Type	Studies	Data Volume	Uses/Findings
(b) (4)			

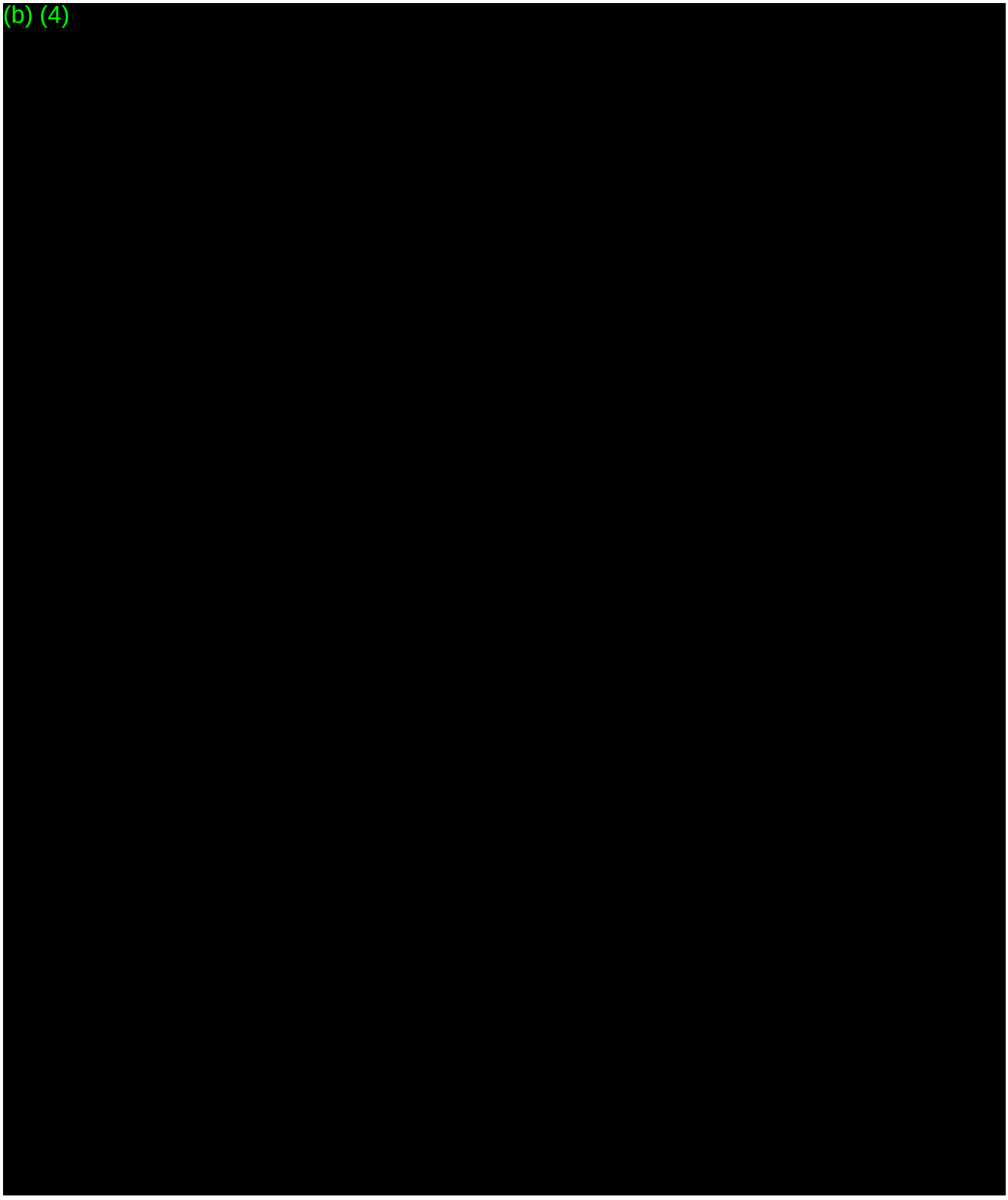
(b) (4)

(b) (4)



(b) (4)

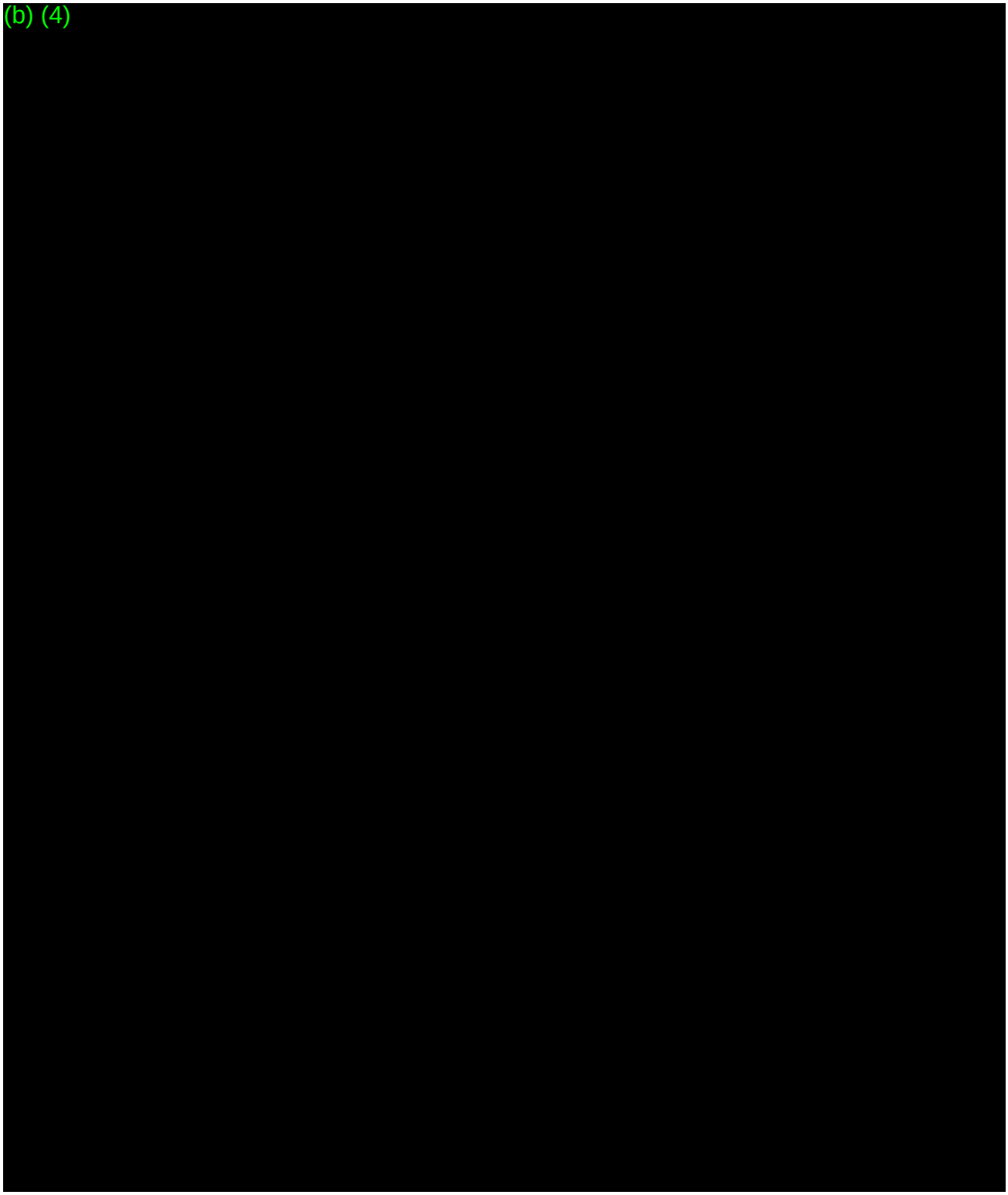
(b) (4)



(b) (4)

[redacted]

(b) (4)



(b) (4)

9.3.2. ECG Performance

(b) (4)

9.3.3. Human Factors Testing

Our HFE/UE Report, per the Guidance "Applying Human Factors and Usability Engineering to Medical Devices," is included in Appendix S. A high level discussion of the results and residual risks are provided below. (b) (4)

9.3.3.1. Tested Product v. Final Product

(b) (4)

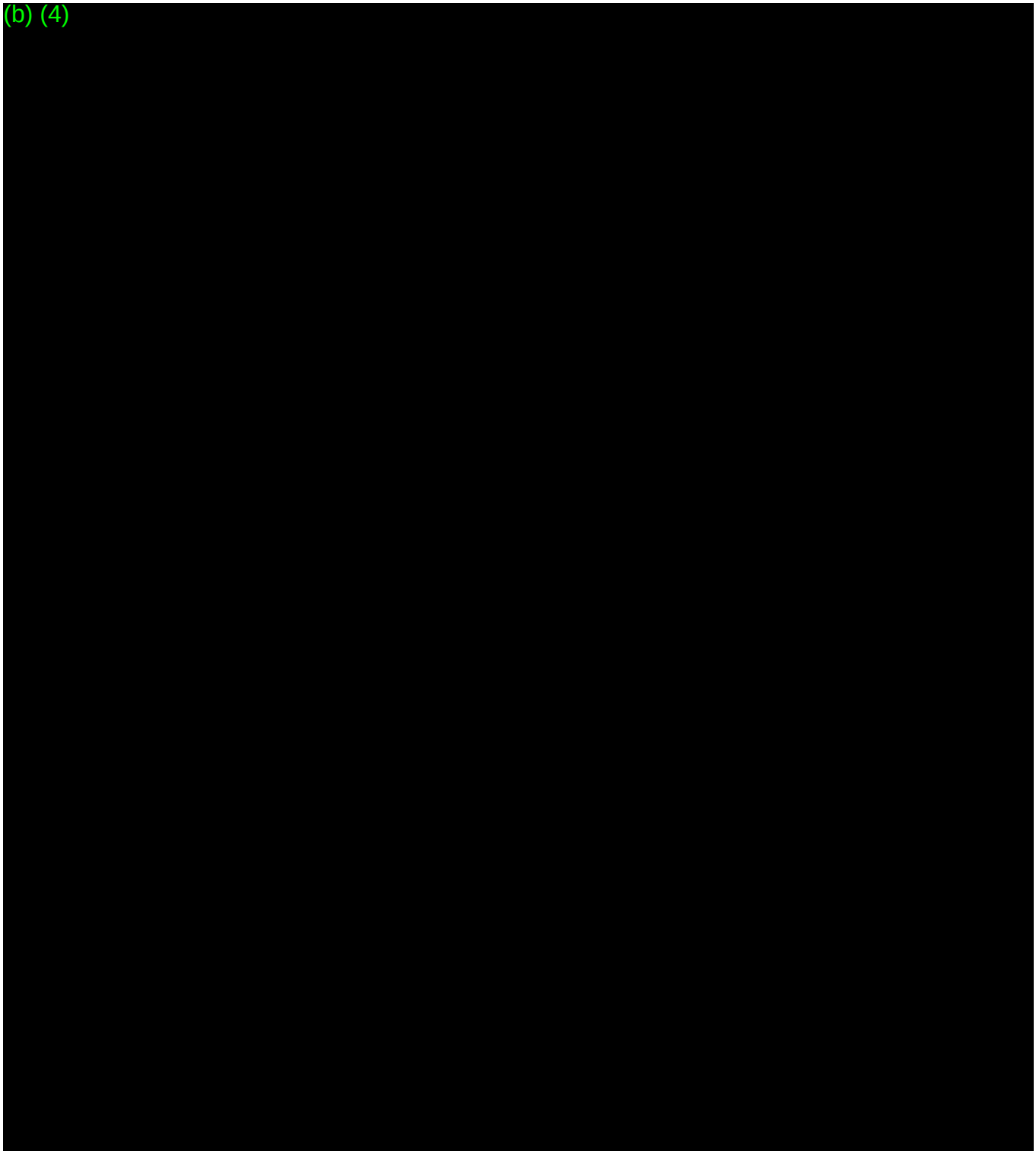
(b) (4)

9.3.3.2. HFE/UE Summary

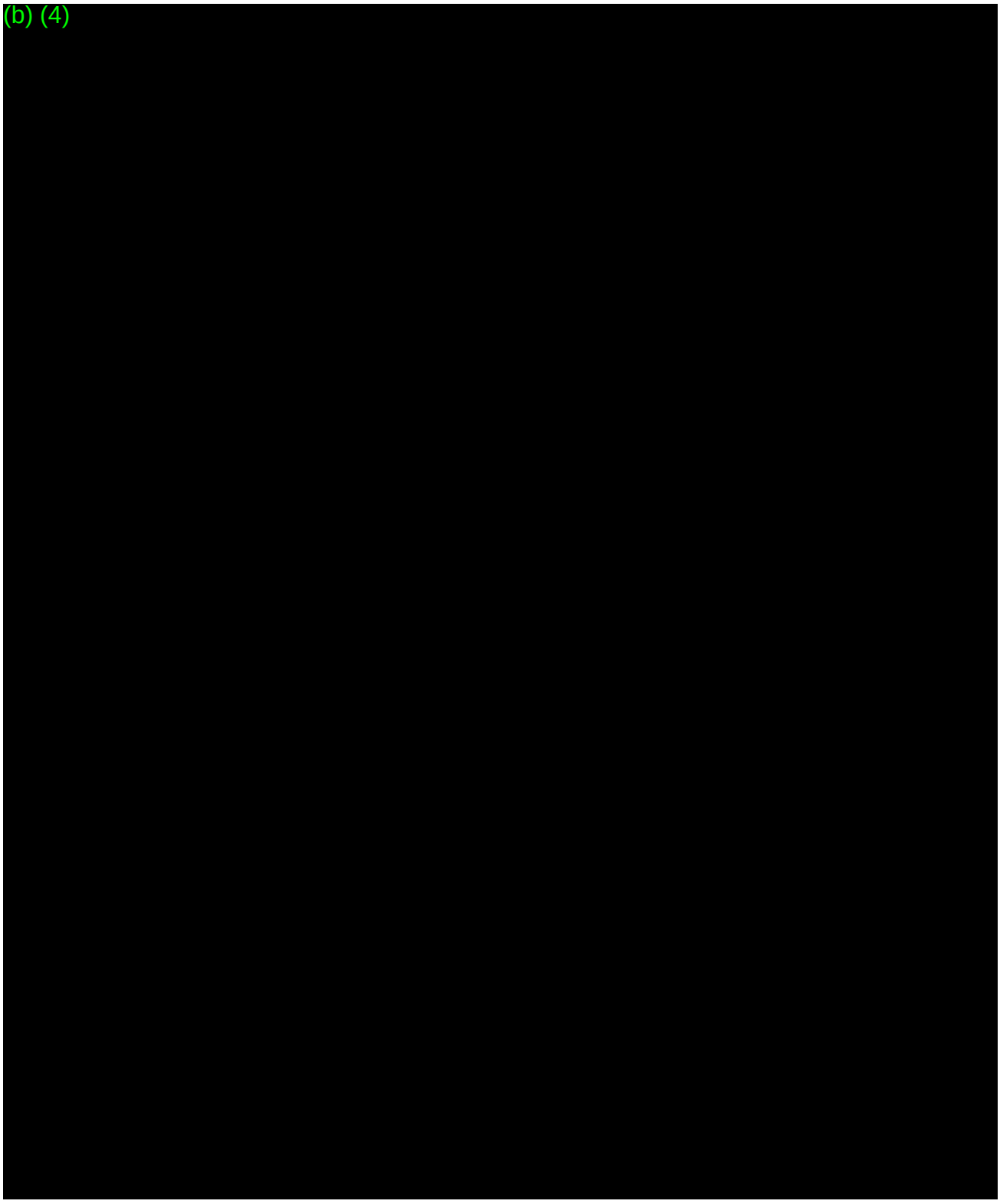
For the Human Factors Validation Study, a total of 50 participants were enrolled (b) (4)

The study represented 3 distinct user groups:

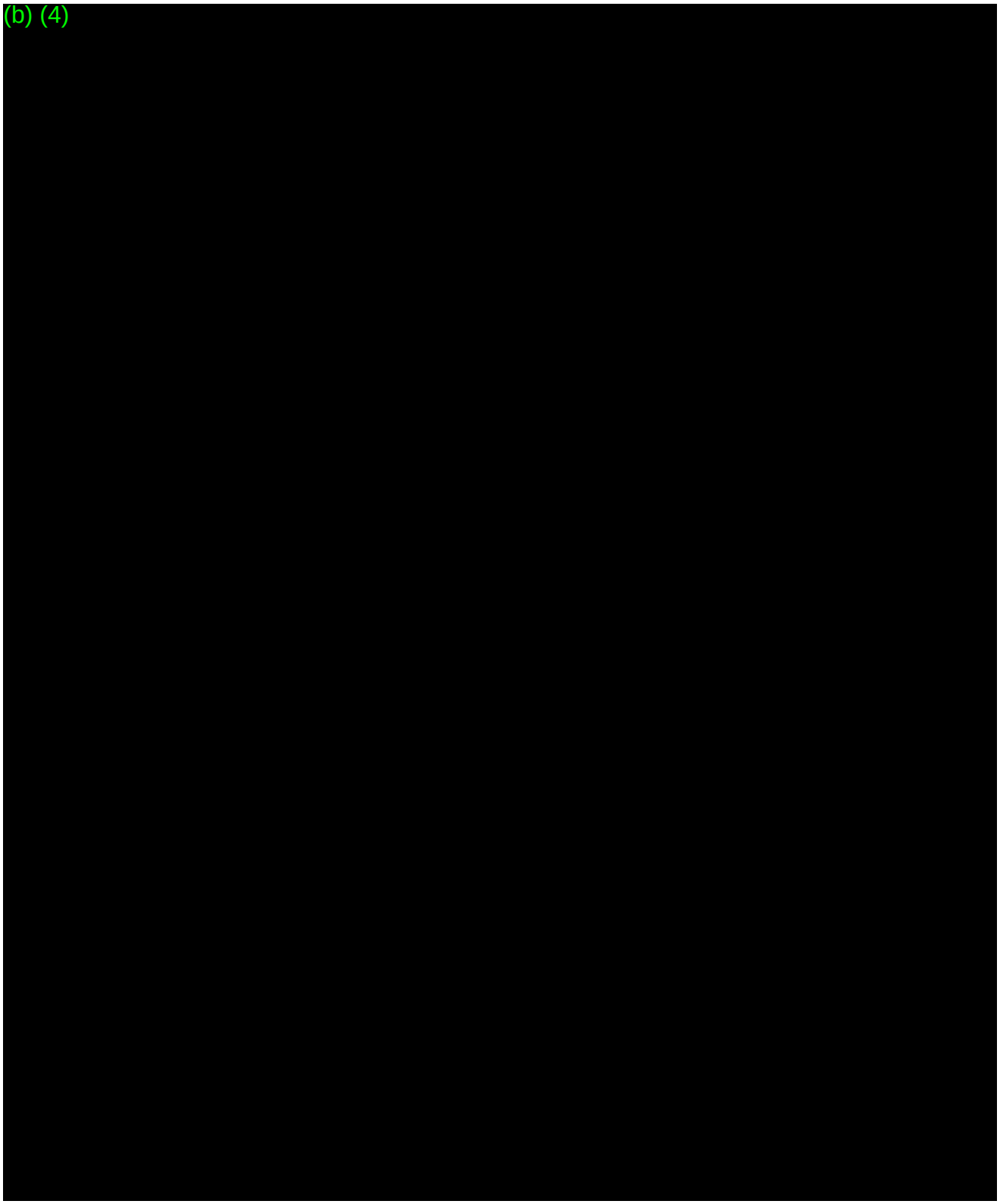
- Group 1 - Users diagnosed with AFib (AFib, n = 17)
- Group 2 - Users age 22-64 (Under 65, No AFib, n = 17)
- Group 3 - Users age 65+ (Over 65, No AFib, n = 16)



(b) (4)



(b) (4)



(b) (4)

9.3.4. Animal

Not applicable.

9.3.5. Clinical

Validation for the algorithm was conducted through both a clinical validation (CV) study and database testing pursuant to the EC57 standard.

9.3.5.1. CV Study Summary

(b) (4)

(b) (4)

Table 9-8 Modified Definitions and UI Output

#	UI Output	Definition	Updated Definition	Algorithm Output
(b) (4)				

(b) (4)

[redacted]

9.3.5.2. CV Study Results

Below are key results from the CV study. The full report is included in Appendix E.

Overall, a total of 602 subjects were enrolled and 588 subjects met all entry criteria to be eligible for study participation. Of the 588 eligible subjects, 301 subjects were assigned to the AF Cohort and 287 subjects were assigned to the SR Cohort. The 14 subjects who completed the study but were not assigned to an enrollment cohort were ineligible for study participation due to a history of paroxysmal AF.

Table 9-9 Summary of Subject Accountability

	AF Cohort at Enrollment	SR Cohort at Enrollment	Overall
Enrolled	301	287	602
Eligible	301	287	588
Completed	301	287	602
Did Not Complete	0	0	0
Adverse Event	0	0	0

Death	0	0	0
Withdrawal of Consent	0	0	0
Investigator Decision	0	0	0
Sponsor Decision	0	0	0
Device Malfunction	0	0	0
Lost to Follow-up	0	0	0
Other	0	0	0

Efficacy analyses were performed using data from the Classifiable and Waveform Assessment Sets. A total of 485 subjects were in the Classifiable Set, including 245 subjects and 240 subjects the AF and SR cohorts, respectively. A total of 126 subjects were in the Waveform Assessment Set, including 61 subjects and 65 subjects in the AF and SR cohorts, respectively.

Table 9-10 Analysis Sets

Analysis Set	AF Cohort at Enrollment	SR Cohort at Enrollment	Overall
All Enrolled	301	287	602
Classifiable	245	240	485
Waveform Assessment	61	65	126

All Enrolled: All subjects who signed informed consent and were enrolled into the study.
Classifiable: All subjects who had readable/classifiable paired SUT and Reference strip from Study Parts C and B-1, respectively.
Waveform Assessment: Randomly selected subjects in Study Part A with readable/classifiable paired SUT and Reference strips.

Table 9-11 summarizes the classifications of the SUT and adjudicated results of the US board-certified cardiologist reads of the ECG reference strips. As pre-defined, the Classification Analysis Set required readable and classifiable strips generated by the DCD and 12-lead ECG. There were 485 such paired strips (highlighted bold in Table 9-11), which were used in the primary endpoint analysis to assess sensitivity and specificity.

Table 9-11 SUT and Reference Strip Classifications

	Reference Strip Final Result				
SUT Alg Class	SR	AF	Other	Unreadable	Total
SR	**238**	**4**	**4**	1	247

AF	**1**	**236**	**2**	2	241
Unclassified	6	7	6	0	19
Unreadable	18	30	1	0	49
Device Result Not Reported*	32	13	1	0	46
Total	295	290	14	3	602

*Results excluded based on pre-established criteria (e.g., Sync not detected) for all but one subject.

A summary of reasons for SUT result not reported for 46 subjects is presented in Table 9-12. This includes data collected during the study that failed protocol adherence or data parsing.

Table 9-12 Summary of SUT Results Not Reported

Exclusion Criterion	Number of Subjects
Paroxsysmal AF protocol deviation	14*
Data Interval < 30 Sec	1
DCD (SUT) Data Inverted	3
Fast Settle Switch Not Detected	12
Filename Cannot be Corrected	1
REF (reference) Data Inverted	8
Signals Not Aligned	2
Sync Not Detected	6*

*Subject 002166 is included in both Paroxysmal AF protection deviation and Sync not detected.

Failure to protocol adherence included paroxysmal subjects enrolled as SR subjects, incorrect filename, and data collected from the devices for less than 30 seconds. Rest of data excluded was during the data parsing. These included data inverted, fast settle switch not detected, reference data inverted, signal not aligned and sync not detected.

Table 9-13 presents demographic characteristics of subjects enrolled in the study. Overall, there were more male subjects (57.1%) than female subjects (42.9%) enrolled, and most subjects were White (90.0%) and not Hispanic or Latino (87.2%). The mean age of subjects in the AF Cohort

(73.8 years) was higher than in the SR Cohort (59.5 years), which was an expected difference for these two groups of subjects.

Table 9-13 Demographic Characteristics – All Enrolled Analysis Set

Characteristic	AF Cohort at Enrollment (N=301)	SR Cohort at Enrollment (N=287)	All Enrolled (N=602)
Age at Enrollment (years)			
N	301	287	602
Mean	73.8	59.5	66.9
Std. Dev.	8.62	17.73	15.47
Median	75.0	65.0	71.0
Min-Max	45 - 92	22 - 91	22 - 92
Age Group [n (%)]			
22-30	0 (0.0)	31 (10.8)	31 (5.1)
31-50	5 (1.7)	47 (16.4)	52 (8.6)
51-64	35 (11.6)	63 (22.0)	102 (16.9)
65+	261 (86.7)	146 (50.9)	417 (69.3)
Sex [n (%)]			
Male	209 (69.4)	128 (44.6)	344 (57.1)
Female	92 (30.6)	159 (55.4)	258 (42.9)
Ethnicity [n (%)]			
Hispanic or Latino	19 (6.3)	57 (19.9)	77 (12.8)
Not Hispanic or Latino	282 (93.7)	230 (80.1)	525 (87.2)

Race [n (%)]*			
American Indian or Alaska Native	2 (0.7)	0 (0.0)	2 (0.3)
Asian	1 (0.3)	2 (0.7)	3 (0.5)
Black or African American	8 (2.7)	46 (16.0)	54 (9.0)
Native Hawaiian or Other Pacific Islanders	0 (0.0)	1 (0.3)	1 (0.2)
White	292 (97.0)	236 (82.2)	542 (90.0)
Not Reported	0 (0.0)	3 (1.0)	3 (0.5)

*Subjects can be represented in more than one category.

Consistent with entry criteria, all subjects in the AF Cohort had a history of heart rhythm abnormalities and most were diagnosed with either permanent AF (58.1%) or persistent AF (34.9%). Most subjects in the SR Cohort (87.5%) had no history of heart rhythm abnormalities of any kind at study entry.

9.3.5.2.1. Primary Efficacy Endpoint Analysis of Sensitivity and Specificity

The sensitivity analysis for the Classifiable Analysis Set resulted in a value of 98.3% (lower confidence bound = 95.8%; Table 9-14). This value was significantly higher than 90% ($p<0.0001$) as pre-specified in the SAP; therefore, the primary sensitivity endpoint was achieved.

Similarly, the specificity analysis for the Classifiable Analysis Set resulted in a value of 99.6% (lower confidence bound = 97.7%; Table 9-14). This value was significantly higher than 92% ($p<0.0001$) as pre-specified in the SAP, so the primary specificity endpoint was also achieved.

Table 9-14 Primary Endpoint Analysis of Sensitivity and Specificity – Classifiable Analysis Set

Parameter	Value	Lower Confidence Bound*	p-value**
Final ECG Reference Result = AF	240		
SUT Device Result=AF	236/240 (98.3%)		
SUT Device Result=SR	4/240 (1.7%)		
Sensitivity	236/240 (98.3%)	95.8%	<0.0001

Final ECG Reference Result = SR	239		
SUT Device Result=AF	1/239 (0.4%)		
SUT Device Result=SR	238/239 (99.6%)		
Specificity	238/239 (99.6%)	97.7%	<0.0001

*Lower exact binomial one-sided confidence bound.
**Test of hypothesis for sensitivity >0.9 and specificity >0.92.

9.3.5.2.2. Additional Exploratory Analysis of Sensitivity and Specificity

An additional exploratory analysis of sensitivity and specificity was performed that included "unclassifiable" device results in the calculations. An "unclassifiable" device result was obtained in 2.8% and 2.4% of subjects in the AF and SR Cohorts, respectively. The results of this analysis are summarized in Table 9-15.

Sensitivity in this additional analysis was 95.5% (95% CI: 92.2%, 97.8%) and specificity was 97.1% (95% CI: 94.2%, 98.8%), which were both consistent with the primary endpoint results.

Table 9-15 Additional Exploratory Analysis of Sensitivity and Specificity

Parameter	Value	Two-Sided 95% Confidence Interval
Final ECG Reference Result = AF	247	
SUT Device Result=AF	236/247 (95.5%)	
SUT Device Result=SR	4/247 (1.6%)	
SUT Device Result=Unclassifiable	7/247 (2.8%)	
Sensitivity*	236/247 (95.5%)	(92.2%, 97.8%)
Final ECG Reference Result = SR	245	
SUT Device Result=AF	1/245 (0.4%)	

SUT Device Result=SR	238/245 (97.1%)	
SUT Device Result=Unclassifiable	6/245 (2.4%)	
Specificity*	238/245 (97.1%)	(94.2%, 98.8%)

*Includes the "unclassifiable" result in the calculation.

9.3.5.2.3. Secondary Efficacy Endpoint Analysis of Subject Success

As shown in Table 9-16, the proportion of subjects with a pass rating based on the visual assessment was 98.4% in the AF cohort and 100% in the SR cohort. The proportion of overall subjects with a pass rating was 99.2% (lower 97.5% confidence bound, 95.7%). Because this value was higher than 80%, the secondary endpoint of subject success was met.

Table 9-16 Secondary Endpoint Analysis of Subject Success – Waveform Assessment Analysis Set

Characteristic	AF Subjects (N=61)	SR Subjects (N=65)	Total (N=126)	Lower Confidence Bound*	p-value**
Number of paired subject strips (SUT and Reference strips) with a pass rating	60	65	125		
Number of readable paired subject strips (SUT and Reference strips)	61	65	126		
Proportion of subject strips with a pass rating	60/61 (98.4%)	65/65 (100%)	125/126 (99.2%)	95.7%	<0.0001
Number of paired subject strips excluded	8	5	13		

*Lower exact binomial one-sided 97.5% confidence bound for Total.
**Test of hypothesis for subject success >0.8.

9.3.5.2.4. Secondary Efficacy Endpoint Analysis of R Amplitude Agreement

As shown in Table 9-17, the agreement proportion of paired strips (paired R-Wave amplitude measurements ≤2 mm of each other) was 95.1% in the AF cohort and 100% in the SR cohort. The proportion of overall subjects with an R amplitude within 2 mm of each other was 97.6% (lower 97.5% confidence bound, 93.2%). Because these values were all at least 80%, the secondary endpoint of agreement proportion was achieved.

Table 9-17 Secondary Endpoint Analysis of R Amplitude Agreement – Waveform Assessment Analysis Set

Characteristic	AF Subjects (N=61)	SR Subjects (N=65)	Total (N=126)	Lower Confidence Bound*	p-value**
Number of paired subject strips (SUT and Reference strips) with an R amplitude within 2 mm of each other	58	65	123		
Number of readable paired subject strips (SUT and Reference strips)	61	65	126		
Agreement proportion of paired strips	58/61 (95.1%)	65/65 (100%)	123/126 (97.6%)	93.2%	<0.0001
Number of paired subject strips excluded	8	5	13		

*Lower exact binomial one-sided 97.5% confidence bound for Total.
**Test of hypothesis for agreement proportion >0.8%.

9.3.5.3. Platform In Use

(b) (4)

(b) (4)

Table 9-18 Platform Evaluation

Difference	Final, Finished Platform	CV Platform
(b) (4)		

9.3.5.4. Representative Device Validation

(b) (4)

(b) (4)

[redacted]

10. SUMMARY OF BENEFITS

Per FDA's guidance document, "Factors to Consider When Making Benefit Risk Determinations in Medical Device Premarket Approval and De Novo Classifications" (Benefit-Risk Guidance), FDA considers the following factors when assessing the probable benefits of the device: the type of benefit, magnitude of benefit, probability of the patient experiencing one or more benefits, and the duration of the effects. Each of these is considered below.

Type of Benefit

Consumers, care providers, and health researchers will benefit from the (b) App and its ability to reach a wide array of users. One of the key benefits of the (b) App is that it allows consumers to take control of their health and empowers them to manage and own their personal health information. It is well understood that access to easy-to-understand health information leads to improved health literacy,[xlviii] an antecedent to patient empowerment and engagement.[xlix] Additionally, the ability to collect, review, and disseminate personalized health information improves self awareness and self-efficacy, which are strong predictors of whether people will take action to prevent, detect, or manage illness conditions.[l] Health literacy, patient empowerment, and self-efficacy have been linked to improved health outcomes across a wide array of disease states.[li]

When users are more engaged in their health and come to the physician armed with information that can provide more context around their heart rhythm, clinicians are able to make better-informed decisions in regards to a patient's care plan. The (b) App can provide this enriched dataset to help physicians glean insights into a patient's symptoms in order to better understand each patient's individual contributors of disease. This enriched dataset combined with subjective history and traditional diagnostics will ultimately lead to the delivery of personalized medicine.

The (b) App may also greatly enhance the tools available to researchers, allowing low cost studies at a scale not easily achievable through traditional devices. It is well known that evidence gaps exist within the field of atrial fibrillation. For example, the USPSTF does not currently recommend ECG screening for Afib. This recommendation was made, however, due to a lack of evidence, as opposed to evidence that does not support mass screening.[lii] Studies to examine the benefits of mass screening, the clinical indicators of poor outcomes, and treatment strategies must be completed. While we do not view our device as a screening device, we do believe our device can facilitate these studies to further enhance and facilitate scientific discoveries that will ultimately impact millions of lives.

Magnitude of Benefit

Palpitations are a frequent symptom in the general population[liii] and their evaluation in primary care settings accounts for 16% of the symptoms that prompt patients to visit their general practitioner.[liv] Most of these patients with palpitations have normal sinus rhythm or other minor rhythm abnormalities. As the prevalence of anxiety syndrome and panic attacks in patients with palpitations ranges from 15-31%,[lv] empowering consumers to learn if they are in sinus rhythm

and to collect data they can share with their physicians during these episodes would provide tremendous benefit to both consumers and providers in piecing together the correlation between palpitations, symptoms, and cardiac rhythms outside of the clinic.

Outside of supporting consumers, we expect this product to be used widely in the research community as a tool to help better study AF, outcomes of AF, and treatment strategies. In this setting, the impact of the (b) App will be large. Adoption of this product will decrease current barriers preventing rapid execution of large-scale research studies on AF. We have spoken to many experts in the field of cardiology, and all have expressed excitement as to the potential this product has to unlock scientific discoveries and advance medical knowledge. These key opinion leaders (KOLs) also felt that the clinical benefits could be many to users. They currently use similar devices on the market to help with elucidating correlation with symptoms and activities for users and they felt the (b) App could make this even easier to do. They found this additional information helpful when reviewing the individual's overall clinical scenario. Furthermore, the KOLs expressed excitement at the potential of studying how these devices could be used to manage patients. They all recognized that many studies would have to be performed but felt the availability of such an app could unlock this type of research at scale. Enabling this type of research would have immeasurable positive benefits in closing evidence gaps.

As noted by the U.S. Preventive Services Task Force (USPSTF), there are not yet trials that have directly assessed the benefit of screening for atrial fibrillation with ECG on clinical outcomes.[lvi] It is therefore difficult to assess the magnitude of the benefit of a pre-screening tool such as the (b) App. Nevertheless, current evidence suggests that AF is undetected in up to 4% of consumers >75 years old[lvii] and devices similar to the (b) App are capable of detecting previously unknown AF.[lviii] While it is unknown how many users <75 years old have undetected AF, it is known that the lifetime risk of developing AF in the U.S. is 25% in men and women 40 years old and greater.[lix] AF is attributed to causing 15% of the 700,000 strokes per year in the United States,[lx] and in those less than 50 years old who have had a stroke, has an incidence as high as 11% with 70% of the AF cohort having paroxysmal AF.[lxi] Younger patients with AF also have a higher mortality than those without a diagnosis of AF.[lxii] A product like the (b) App could significantly reduce the morbidity and mortality associated with undetected AF in both younger and older populations.

Probability of the patient experiencing one or more benefits

Providing consumers with a way to track and monitor palpitations and other symptoms could lead to decreased anxiety. As palpitations are a frequent symptom in the general population, the probability of a general consumer experiencing benefit is high.

While the majority of palpitations are not caused by arrhythmias, a large percentage of palpitations (10-16%)[lxiii] could potentially be due to AF. The challenge in screening for and diagnosing arrhythmias such as AF lies in capturing a recording of the cardiac rhythm while a

user is having symptoms. By providing users with this ability to rapidly record ECGs, the (b) App has the ability to provide consumers with a higher fidelity of relevant data that can be presented to clinicians. While the probability of this benefit is hard to quantify, it is likely that every user who experiences symptoms would benefit while users in the 65+ age range will experience the most benefit as they are the users most likely to experience arrhythmias such as AF.

Duration of effects

Early detection and treatment of patients with AF minimizes risk of sequelae of thromboembolism including >60% reduced risk of stroke.[lxiv,lxv] The individual will be able to take the results to their clinician, who can confirm the diagnosis and begin treatment as deemed appropriate. Therefore, once the (b) App accurately identifies an individual as having AF, the effect of that early detection may positively influence the remainder of the individual's life.

For those experiencing palpitations, the app can likewise provide individuals with enriched data to present to their clinicians to aid in the workup and diagnosis of the cause of an individual's palpitations. Knowledge of an individual's own health can relieve anxiety but the length of time for which it relieves this anxiety is difficult to quantify.

Additionally, any scientific discoveries and medical advances made through use of this device could effect the screening, diagnosis, and management of AF for decades.

11. SUMMARY OF IDENTIFIED RISKS TO HEALTH

The risk assessment process for the (b) App included evaluation of product design risks, usability risks, and cybersecurity risks. OTS software was also considered as part of the risk assessment taking into account the FDA guidance on OTS Software Use in Medical Device.

A copy of the risk assessment, including mitigations, post-mitigation risk occurrence and severity, traceability of the mitigations, and residual risks, is provided in Appendix H.

An updated (from Module 1) summary table is provided below.

Potential Hazard	Reason for Risk	Harm
(b) (4)		

Potential Hazard	Reason for Risk	Harm
(b) (4)		

FDA's Benefit-Risk Guidance sets forth the criteria by which it assesses the extent of the probable risks or harms of the device. These criteria are discussed in turn below.

Severity, types, number and rates of harmful events associated with the use of the device

The risk assessment in Appendix H provides a detailed discussion of the severity, types, and probability of occurrence for the potential risks associated with the (b) App. This section addresses only the risks expected to be either more severe or to occur with greater frequency.

As discussed in section 11.1 below, a search of the MAUDE database indicates that there have been only three MDRs reported for the AliveCor ECG monitor since February 1, 2014. All three related to erroneous results, one of which resulted in a user with a history of anxiety experiencing a panic attack.

These results are consistent with the severity, types, number, and rates of events expected to be experienced with the (b) App. The nature of the device is not one that is likely to lead to serious or life-threatening events. An asymptomatic individual who uses the (b) App and learns of possible atrial fibrillation will be instructed to speak with a clinician about the results. It is expected that the clinician will determine the appropriate diagnostic tests and treatment course in line with current standards of care.

Given that the condition (atrial fibrillation) is one for which over-the-counter treatments are not available, it is improbable that individuals will have the ability to "self-treat" upon learning of possible atrial fibrillation. Nevertheless, in an abundance of caution, the (b) App risk analysis does contemplate that there may be individuals who, upon learning of a possible atrial fibrillation diagnosis, may self-treat with, for example, an OTC blood thinner, such as aspirin. If this were to occur and if the individual were to take the aspirin consistent with the product's labeling, it is unlikely that the individual would experience serious harm as a result. It is also possible that someone previously prescribed medication for AF would take their medication in response to an AF classification. From a clinical perspective, doing so is not likely to cause serious harm.

It is also possible that someone experiencing acute symptoms relies on a classification of sinus rhythm or inconclusive and fails to contact emergency medical services, despite being directed to do so by the product labeling. This is likely to be the most serious harm event associated with use of the device, and one that is expected to occur infrequently. As discussed above in Section 9.2.2., human factors testing showed that a limited number of individuals may delay or alter care in response to a finding of sinus rhythm or inconclusive. In nearly all cases, however, the individual ultimately did seek care, either by contacting their doctor or going to the hospital, and the types of use events seen in human factors testing are not likely to present serious harm to the user.

Probability of a harmful event

FDA's guidance document defines probability as "the proportion of the intended population that would be expected to experience a harmful event" and further notes that "FDA would factor whether an event occurs once or repeatedly into the measurement of probability." As reflected in the hazard analysis, the probability of a harmful event occurring as a result of use of the device is low.

The most likely harmful event is a user experiencing anxiety upon learning of a possible atrial fibrillation diagnosis. While it is difficult to quantify precisely the probability of this event occurring, information gathered as part of the Apple Heart Study (AHS) may be applicable to the (b) App. AHS (NCT03335800) is a prospective, single arm, experimental, non-significant risk study conducted to evaluate whether the AHS App can use data collected on the Apple Watch to identify irregular heart rhythms, including those from potentially serious heart conditions such as atrial fibrillation. At the time of this submission, the study is active and ongoing. Data from the study will be submitted to the FDA in a separate de novo submission.

The algorithm contained within the AHS App is a background, opportunistic measurement, as compared to (b) which is on-demand. Nevertheless, the possible result is the same: an asymptomatic individual not previously diagnosed with atrial fibrillation receives information from the app indicating that AF may, in fact, be present. Preliminary data from AHS indicates that, with an enrollment of approximately 436,000 individuals, only 9 have reported anxiety

related to use of the app. A similarly low probability of anxiety-related events may reasonably be expected through use of the (b) App.

(b) (4)

[redacted]

11.1. MAUDE Database Search

The most similar device on the market is the AliveCor device, different only in that the AliveCor offers a "physician in the loop option" and is therefore marketed as both an Rx and OTC device.

A search of this device back to February 1, 2014, uncovered only three MDRs. All three were related to erroneous results, one of which resulted in the user having a panic attack when the app incorrectly classified her rhythm as atrial fibrillation.

12. RISK AND MITIGATION INFORMATION

The key identified risks to health and proposed mitigation measures are noted below. For a more complete description of the risks to health, please see the risk assessment document, included in Appendix H, as well as the Human Factors summative testing protocol, included in Appendix F.

Potential Hazard	Recommended Mitigation Measure	Supporting Data contained in the De Novo (section, page number)
(b) (4)		

Potential Hazard	Recommended Mitigation Measure	Supporting Data contained in the De Novo (section, page number)
(b) (4)		

13. BENEFIT-RISK CONSIDERATIONS

As discussed above, FDA's guidance document, "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications," outlines the factors FDA considers when making benefit-risk determinations. Importantly, FDA notes that when making benefit-risk determinations, it considers "probable" risks and benefits, not "theoretical" risks and benefits.

The probable benefits and risks of the device have been discussed in detail in the sections above. FDA also describes additional factors that it considers when assessing the probable benefits and risks of devices. Relevant additional factors are discussed below.

Uncertainty

FDA considers the degree of certainty of the benefits and risks of a device, while recognizing that it is not possible to be 100% certain of a device's reasonable assurance of safety and effectiveness. As described above, the greatest probable benefit offered by the (b) App is the ability for people to take an ECG at their convenience and share the results with their doctor, thereby increasing the likelihood of early detection of AF. The clinical validation data demonstrate a high degree of sensitivity and specificity.

Characterization of the disease

As discussed above in section 6, AF is the most common cause of stroke, and many individuals are not diagnosed with AF until the stroke event. Identifying AF prior to the occurrence of stroke not only will improve quality of life for those diagnosed, but will also reduce costs on the healthcare system. Given that AF can often progress in an asymptomatic manner, providing individuals with the ability to potentially identify AF prior to experiencing symptoms is of critical importance.

Large-scale adoption of (b) App usage can enable low-cost long-term research on outcomes including personalized intervention strategies that could potentially decrease adverse events associated with current therapies, differences in outcomes in those with subclinical AF detected through mass screening mechanisms compared to those discovered through current clinical practice mechanisms, and the benefits and risks of primary and secondary prevention of stroke in asymptomatic AF individuals. Furthermore, this App could allow for scientific investigators to better answer the question of whether early detection coupled with a better understanding of an individual's burden of AF ultimately improve medical outcomes. Sensing disease before it happens is the premise of precision medicine and this App is one of the first steps in the scientific investigation to support that vision. Apple welcomes the opportunity to discuss with FDA how to leverage use of this novel product to further explore these and other long-term research goals.

Availability of alternative treatments or diagnostics

While there are other ECG devices on the market, none are available OTC. Prior to the availability of the (b) App, most individuals will never be given access to an Rx ECG device until after they have been diagnosed with a disease. By making ECG technology available more broadly, individuals may have the opportunity to learn of an important disease state before becoming symptomatic, can correlate their symptoms with their lifestyle, and will have the ability to share that information with their clinician in order to determine the right course of diagnostics and treatment.

In sum, the primary benefits of the device are clear: it allows asymptomatic individuals to learn about the possible presence of AF well before such diagnosis would be made during standard clinical care, and it allows users with intermittent symptoms to capture clinically meaningful data at the moment their symptoms are present. Currently, if a person is asymptomatic and not in an at-risk group, there would be no reason to screen them for AF or have them undergo an ECG, since neither are part of the standard clinical workflow. Typically, individuals are only checked for AF when they feel symptoms or when their doctor detects there may be an issue. By leveraging wearable technology that makes it easy for people to take control of their health and check their ECG at their convenience, a user may learn about AF far earlier than would otherwise have occurred. By learning about possible AF early, clinicians may be able to intervene at an earlier stage to prevent longer term harm that may otherwise result from undetected atrial fibrillation. This is the biggest advantage of the (b) App.

As described in the hazard analysis and above, the probable risks associated with use of the device are minimal, and relate primarily to anxiety that may be experienced upon learning of a possible AF diagnosis. Risks that are present will be mitigated against through use of the specified special controls.

Given the importance to the public's health of identifying and treating AF early, the benefits of having a device in the hands of users that will allow for earlier identification far outweigh the possible probable risks associated with the device.

14. PROPOSED LABELING

The (b) App experience can be found in Appendix D. Instructions for Use is provided in Appendix O.

15. DEFINITIONS

Term	Definition
AF	Atrial fibrillation
AHS	Apple Heart Study
BPM or bpm	Beats per minute
ECG	Electrocardiogram
EMC	Electromagnetic Compatibility
ESC	European Society of Cardiologists
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FHIR	Fast Healthcare Interoperability Resources
HealthKit	HealthKit is a public framework included with iOS that is used to store, manage, and share heath and fitness data. Data stored in HealthKit can be viewed in the Health app.
HITECH	Health Information Technology for Economic and Clinical Health
HHS	U.S. Department of Health and Human Services
HR	Heart rate
ICM	Implantable cardiac monitor
MAUDE	Manufacturer and User Facility Device Experience Database
Regular Rhythm	Normal sinus rhythm
OAC	Oral anticoagulation
OTC	Over-the-counter
OTS	Off-the-shelf Software

Term	Definition
PAF	Paroxysmal atrial fibrillation
Paired iPhone	A paired iPhone refers to a user's iPhone that is connected to the user's Apple Watch
PPG	Photoplethysmography
P-wave	Section of the ECG representing atrial contraction
QRS	Section of the ECG representing ventricular depolarization
SDS	Software design specification
Session result	Includes clinically equivalent waveform, average BPM, and rhythm classification.
(b) App	(b) App refers to (b) iPhone App and (b) Watch App collectively.
(b) iPhone App	(b) iPhone App includes the (b) UI framework and ECG portion in the Health App.
(b) Watch App	(b) Watch App is a software application that runs on the Apple watchOS operating system.
SRS	Software requirements specification

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: June 30, 2020
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
August 13, 2018	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☒ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
(b) (4)			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Biologics Consulting Group			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	410-531-6542		
Street Address	FAX Number *(including area code)*		
1555 King Street, Suite 300			
City	State / Province	ZIP Code	Country
Alexandria	VA	22314	US
Contact Name			
Donna-Bea Tillman			
Contact Title	Contact E-mail Address		
Senior Consultant	dtillman@biologicsconsulting.com		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information
1		2		3		4		☐ 510 (k) summary attached
5		6		7		8		☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1		1		1	
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Electrocardiograph transmitter and receiver

	Trade or Proprietary or Model Name for This Device		Model Number
1	(b) (4) App	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 (b) (4)	2 (b) (4)	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
DXH	21 CFR 870.2920	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Cardiovascular

Indications *(from labeling)*

See Appendix B

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Form Approved: OMB No. 0910-0511 Expiration Date: August 31, 2019. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

Biologics Consulting Group, Inc.
1555 King St
Suite 300
Alexandria
VA
VA 22314
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****3476

2. CONTACT NAME
Calley Herzog
2.1 E-MAIL ADDRESS
cherzog@biologicsconsulting.com
2.2 TELEPHONE NUMBER (include Area code)
720-8833633
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[ ] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice
[X] De Novo Request

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)
[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing

the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) [redacted] 16-Jul-2018

Form FDA 3601 (08/16)

"Close Window" Print Cover sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
N/A. This is a De Novo Submission

Device Name
(b) (4)

Indications for Use *(Describe)*
(b)(4) Draft

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Appendix C: Meeting Minutes

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Appendix H: Device Hazard Analysis

Revision History

Version #	Updates
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Appendix I: (b) (4) Software Requirements Specifications

Definitions

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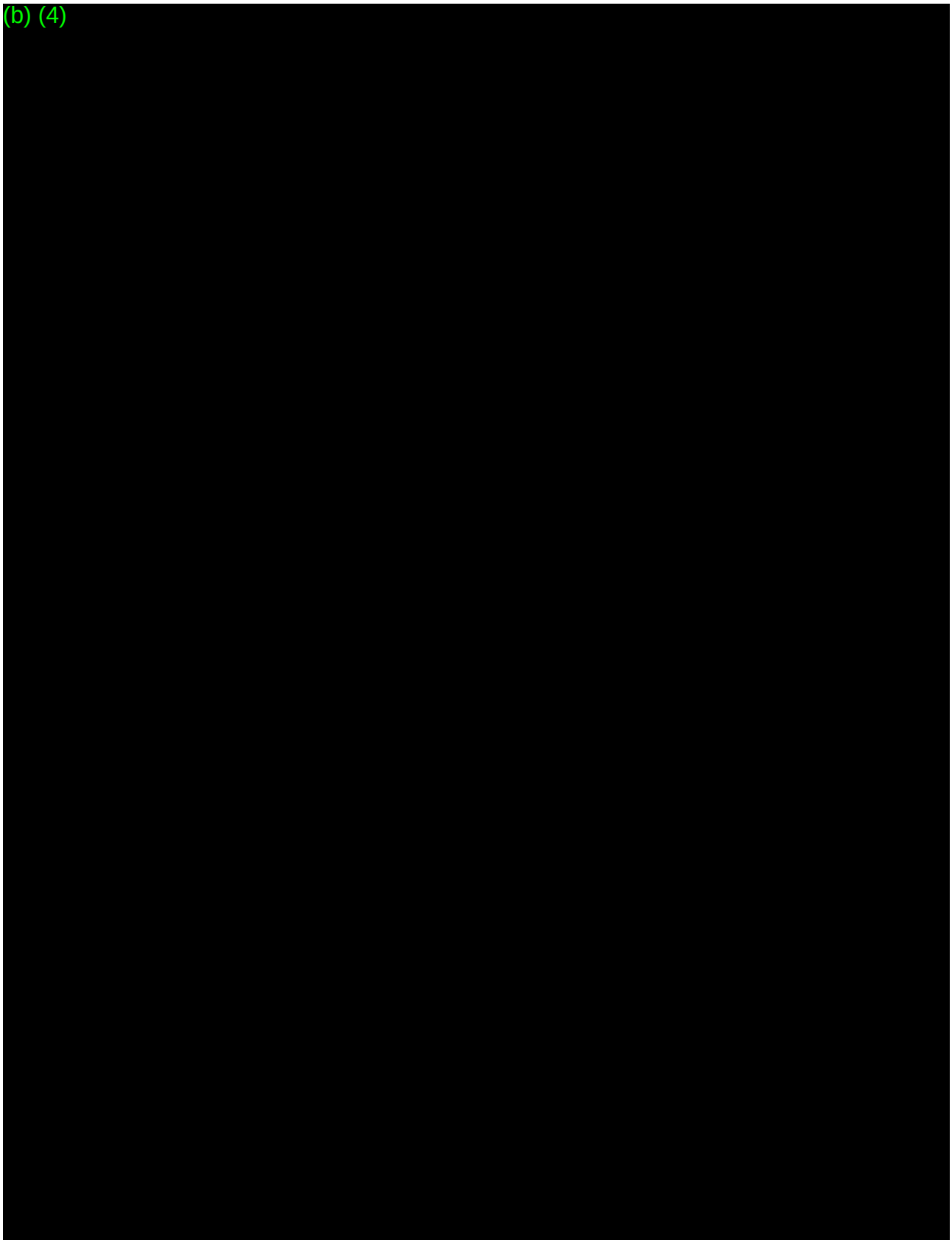

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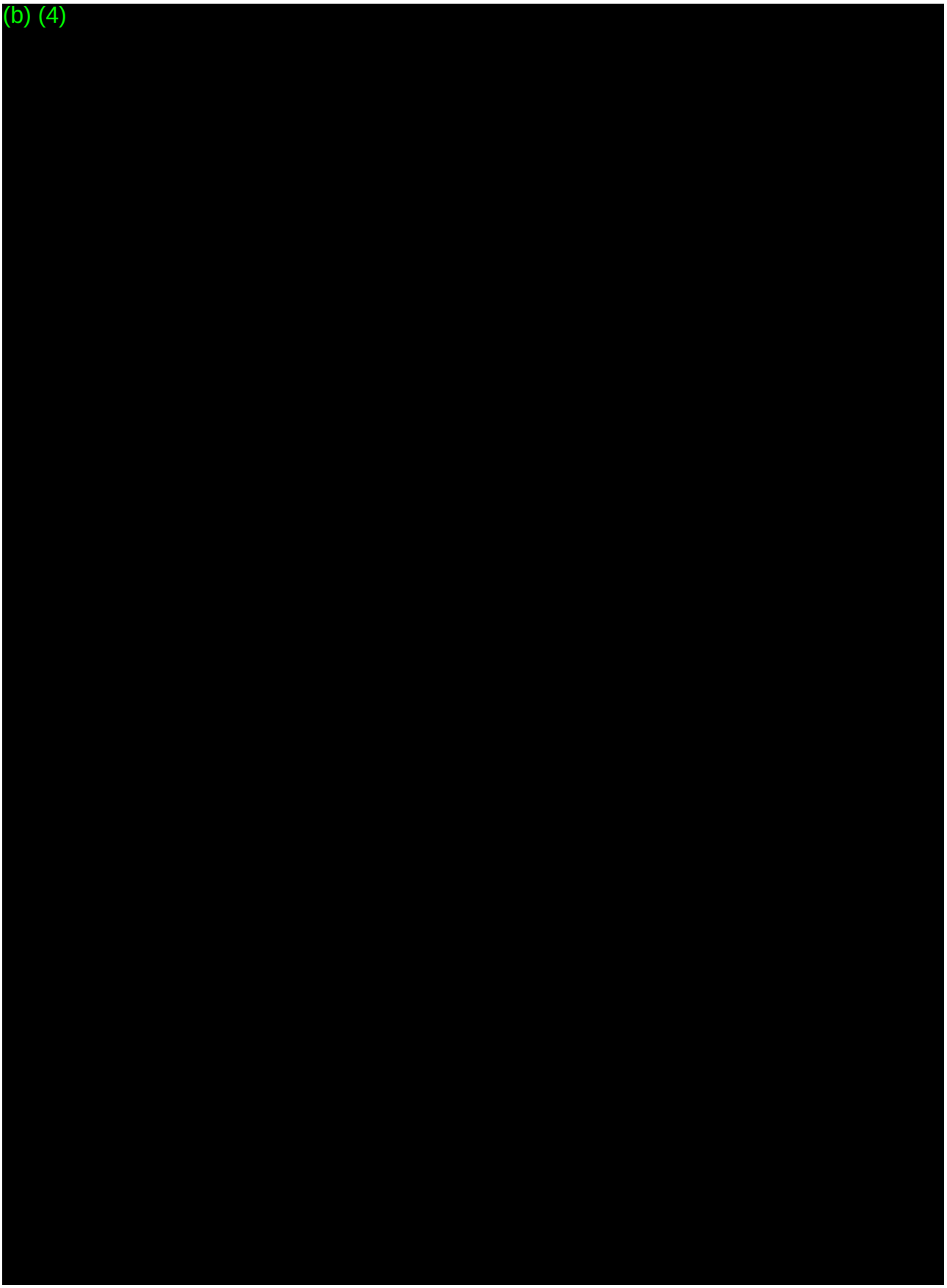

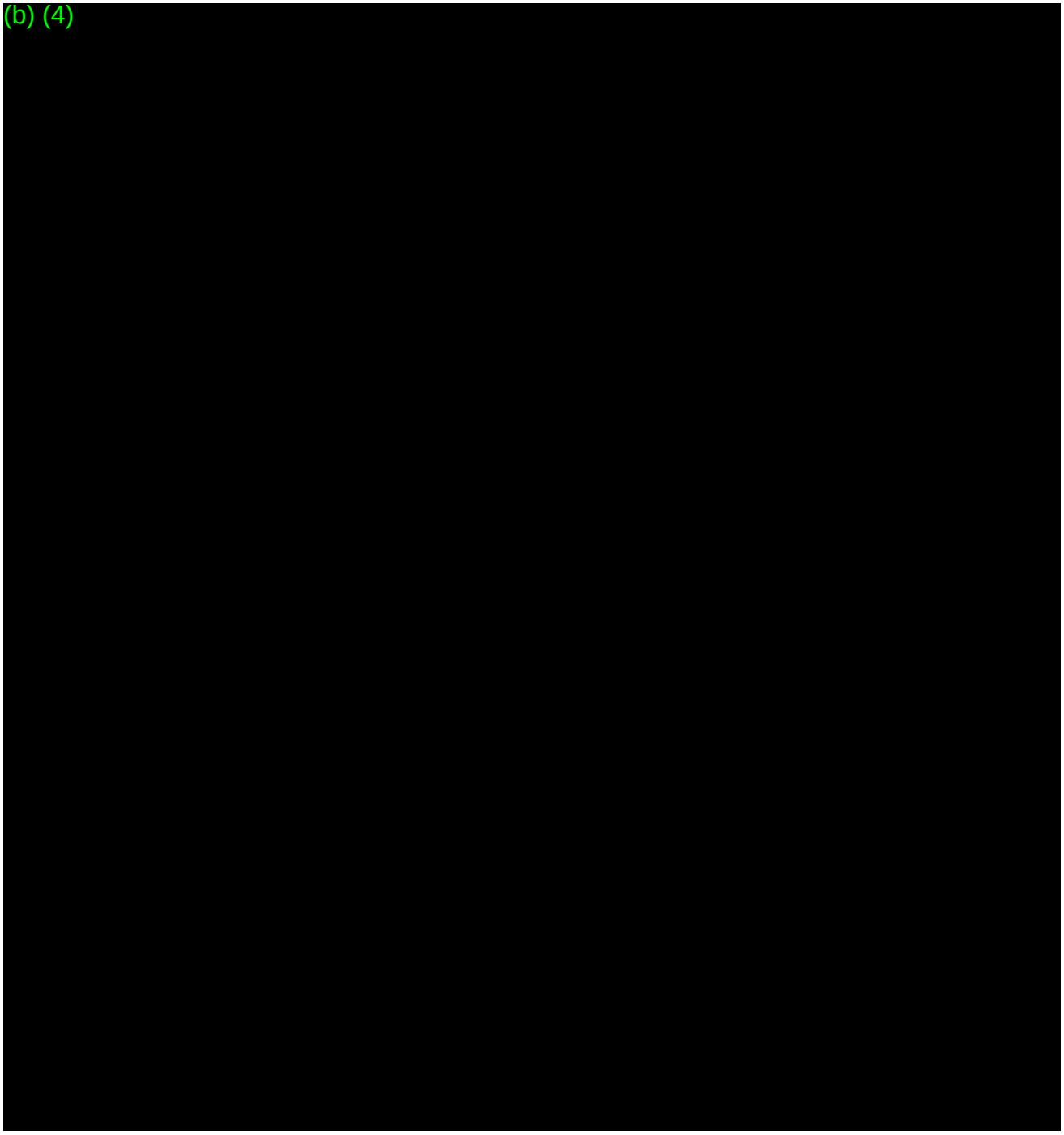

Platform Requirements

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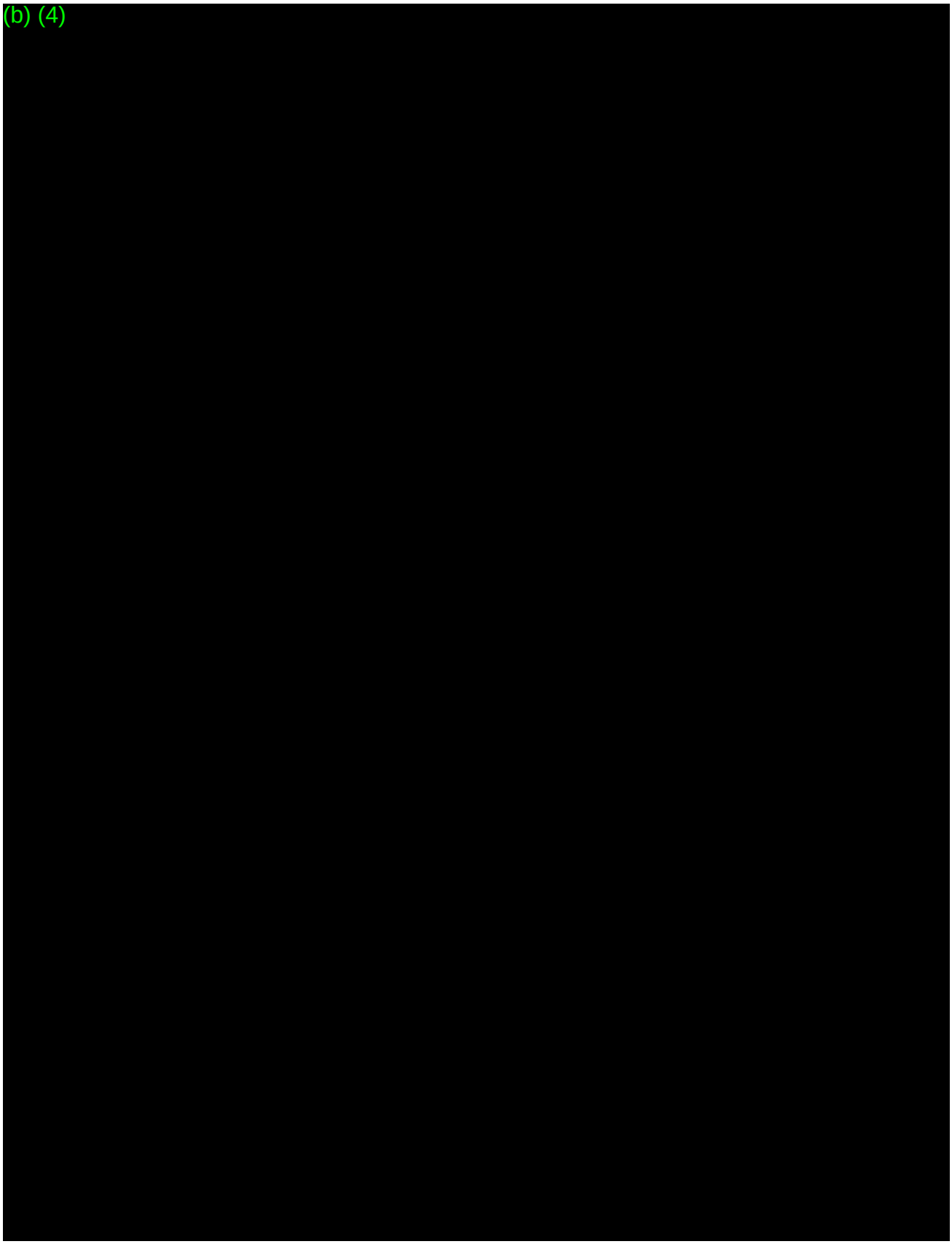

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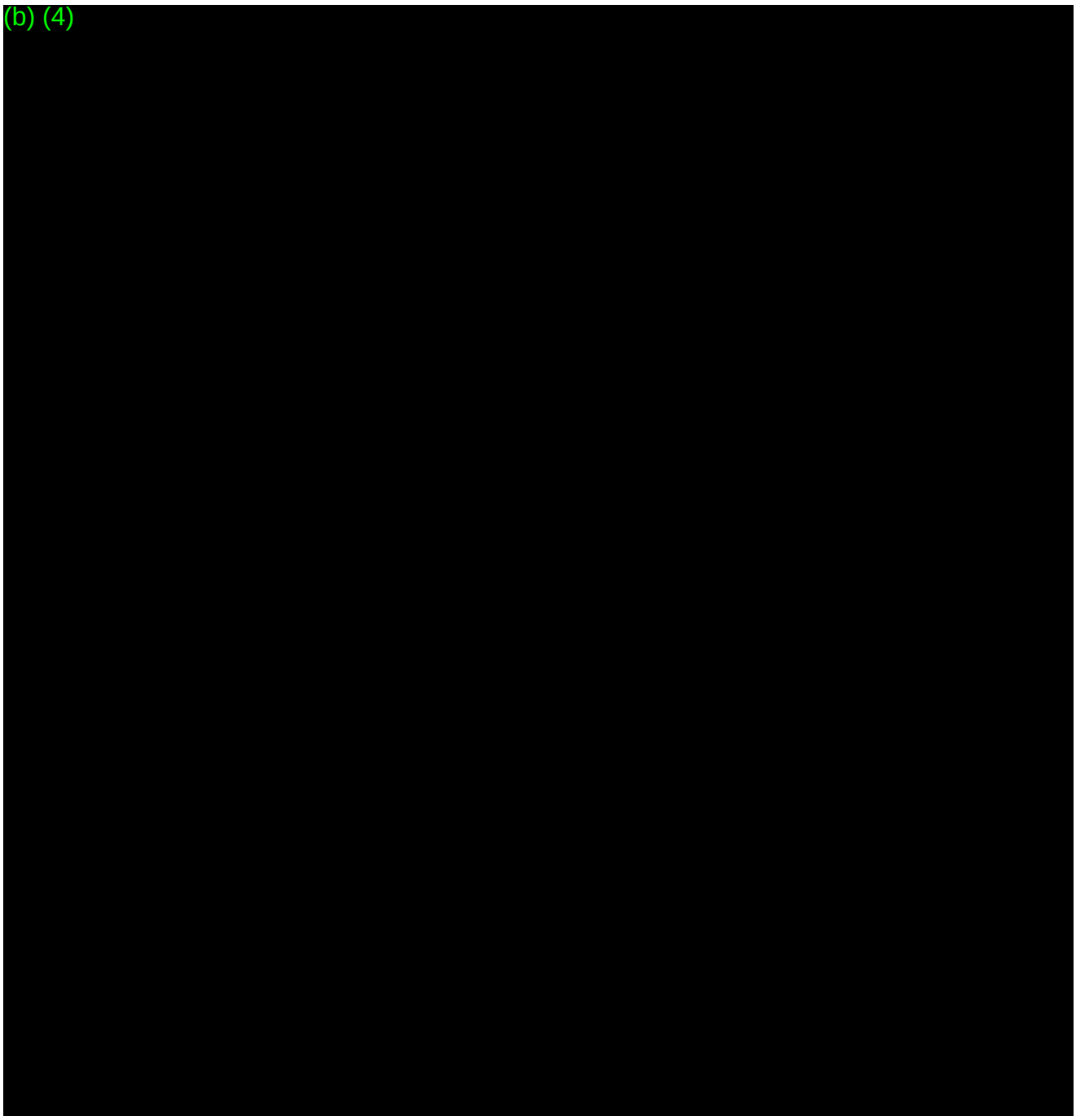

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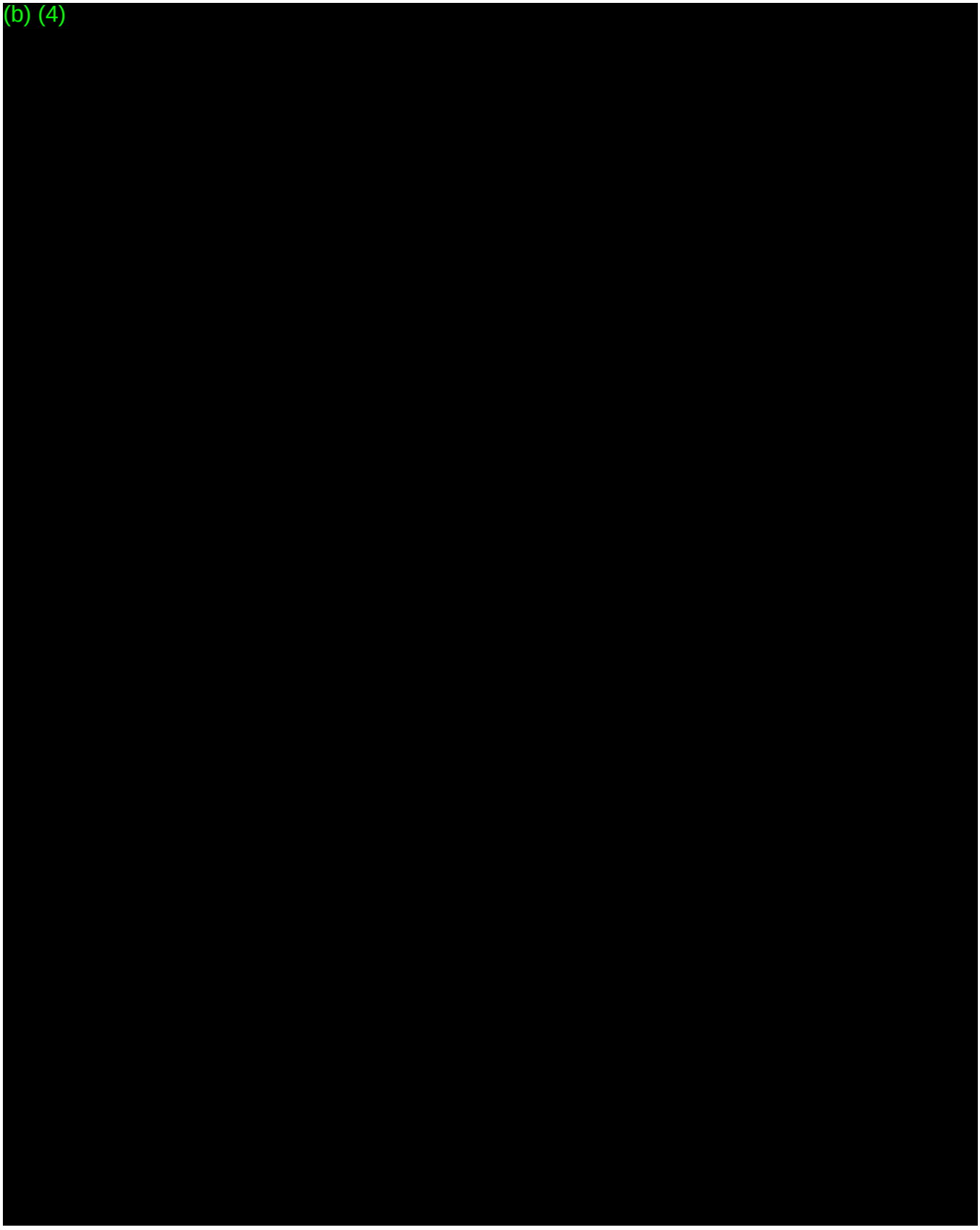

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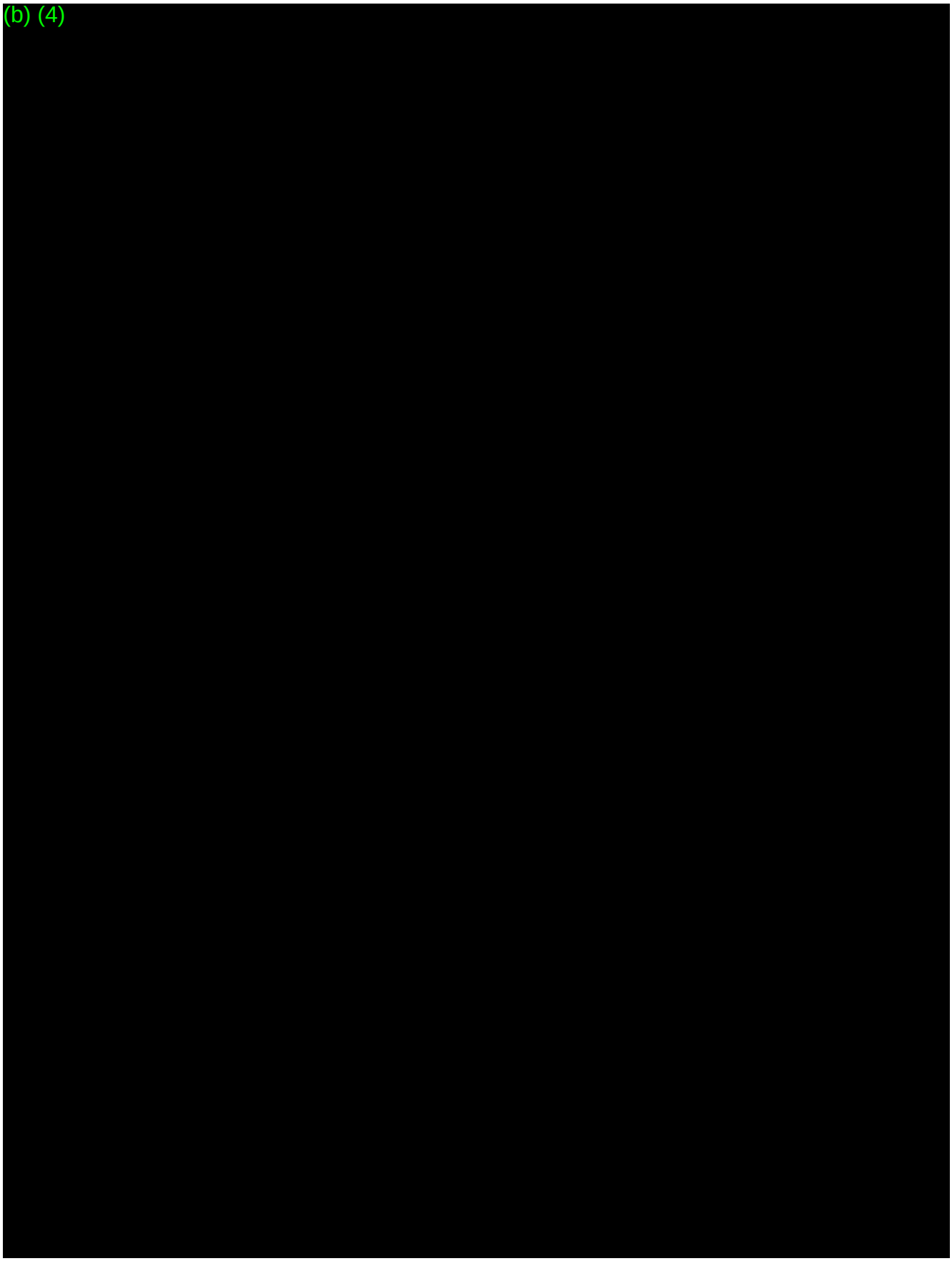

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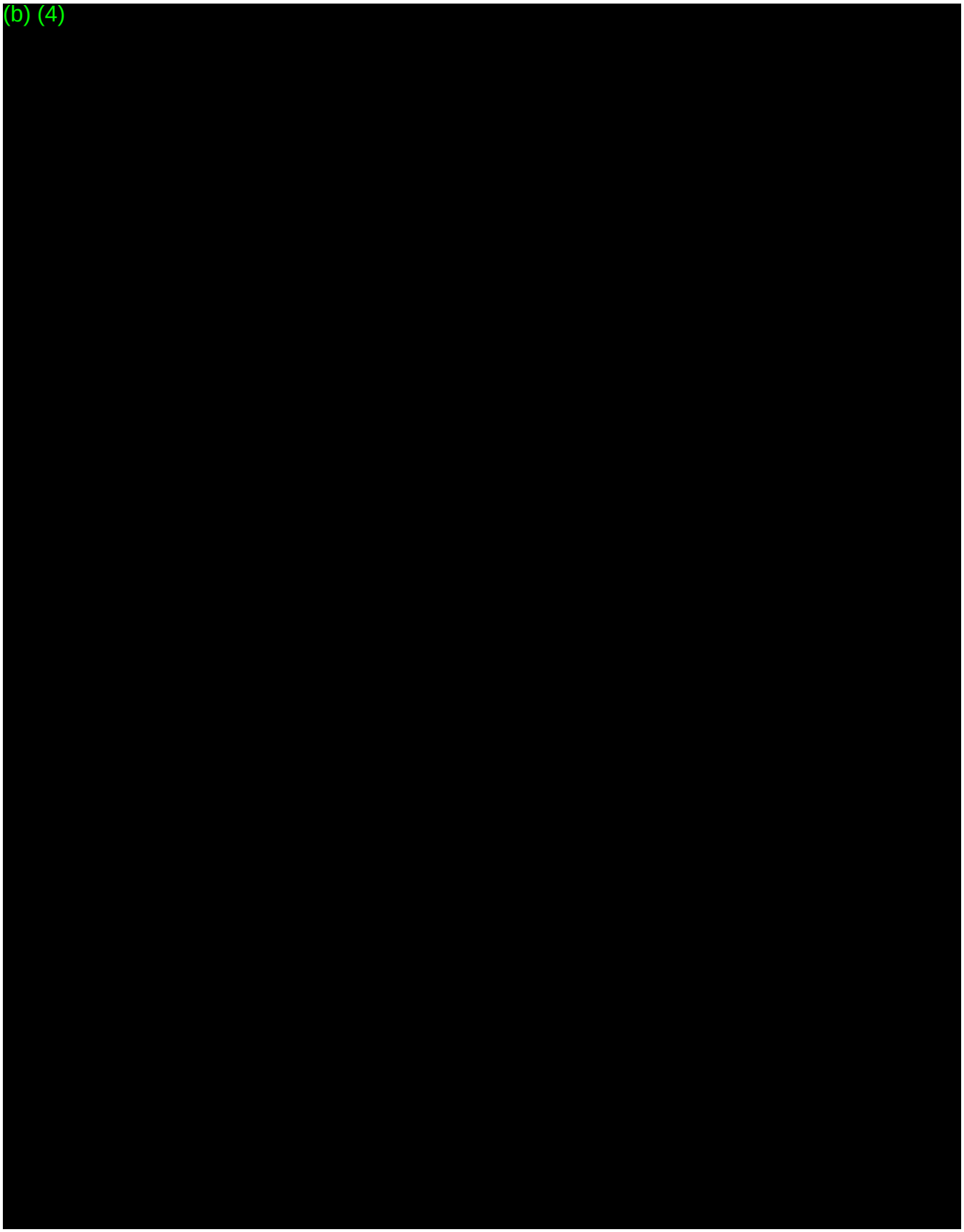

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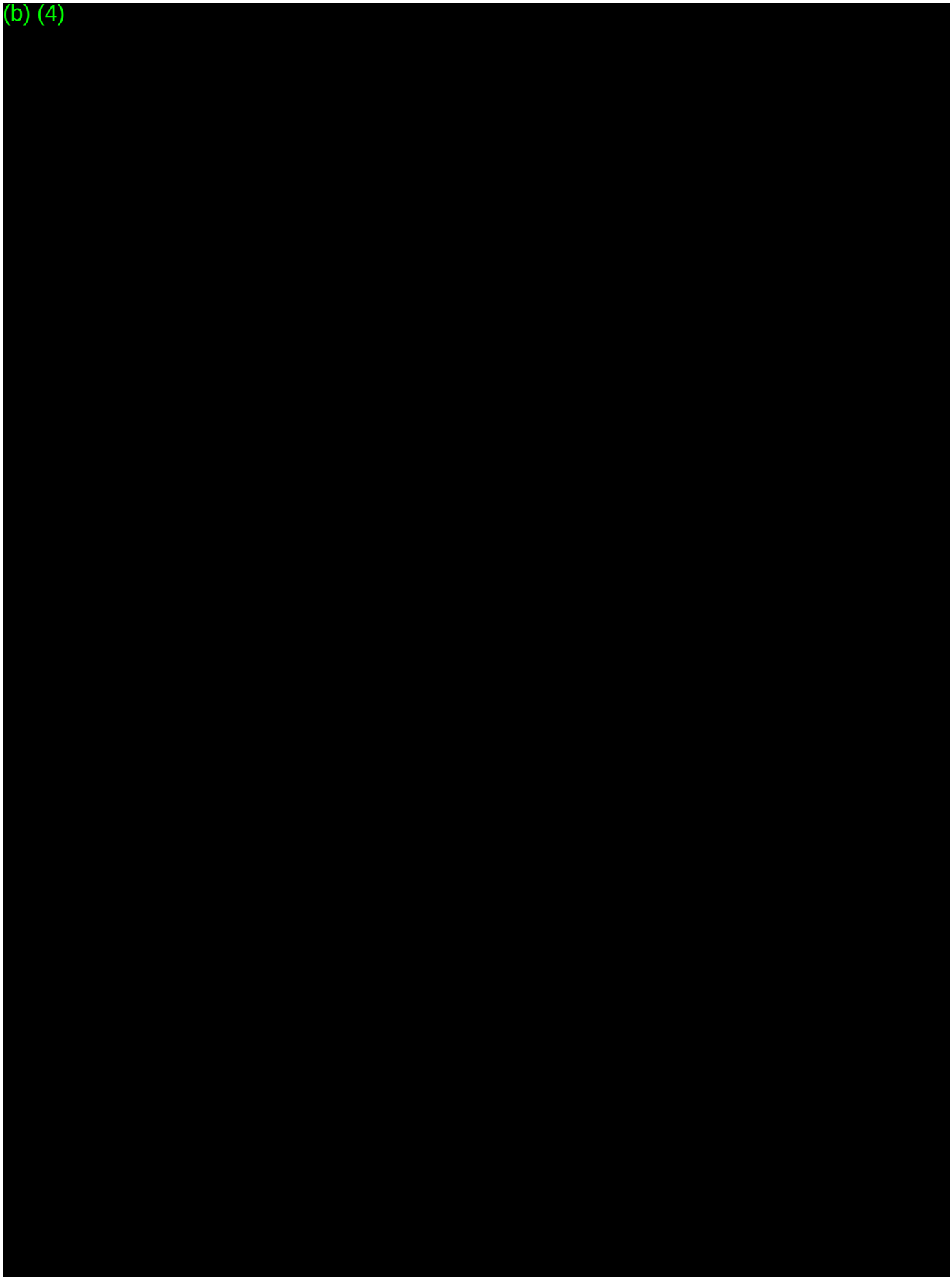

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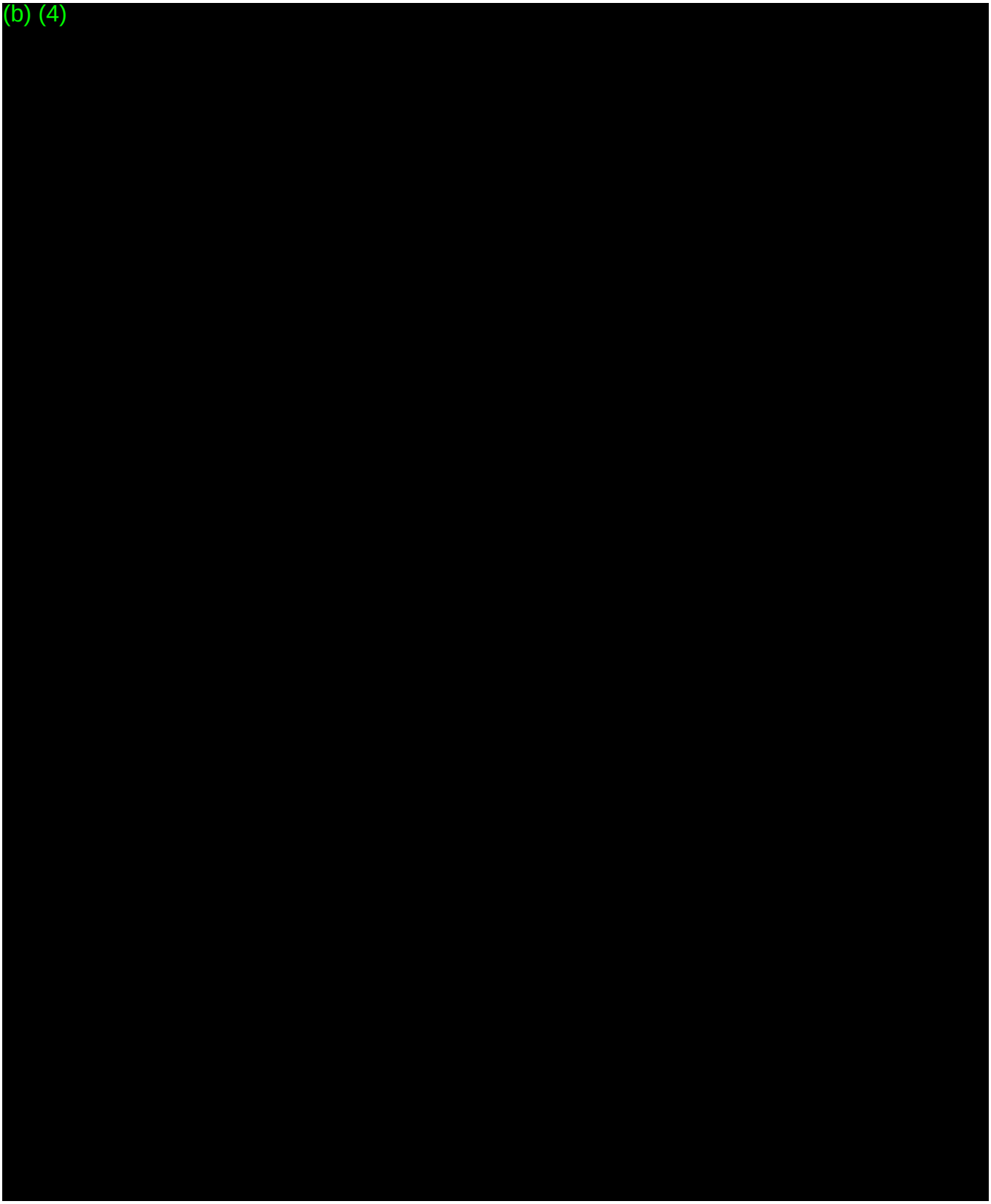

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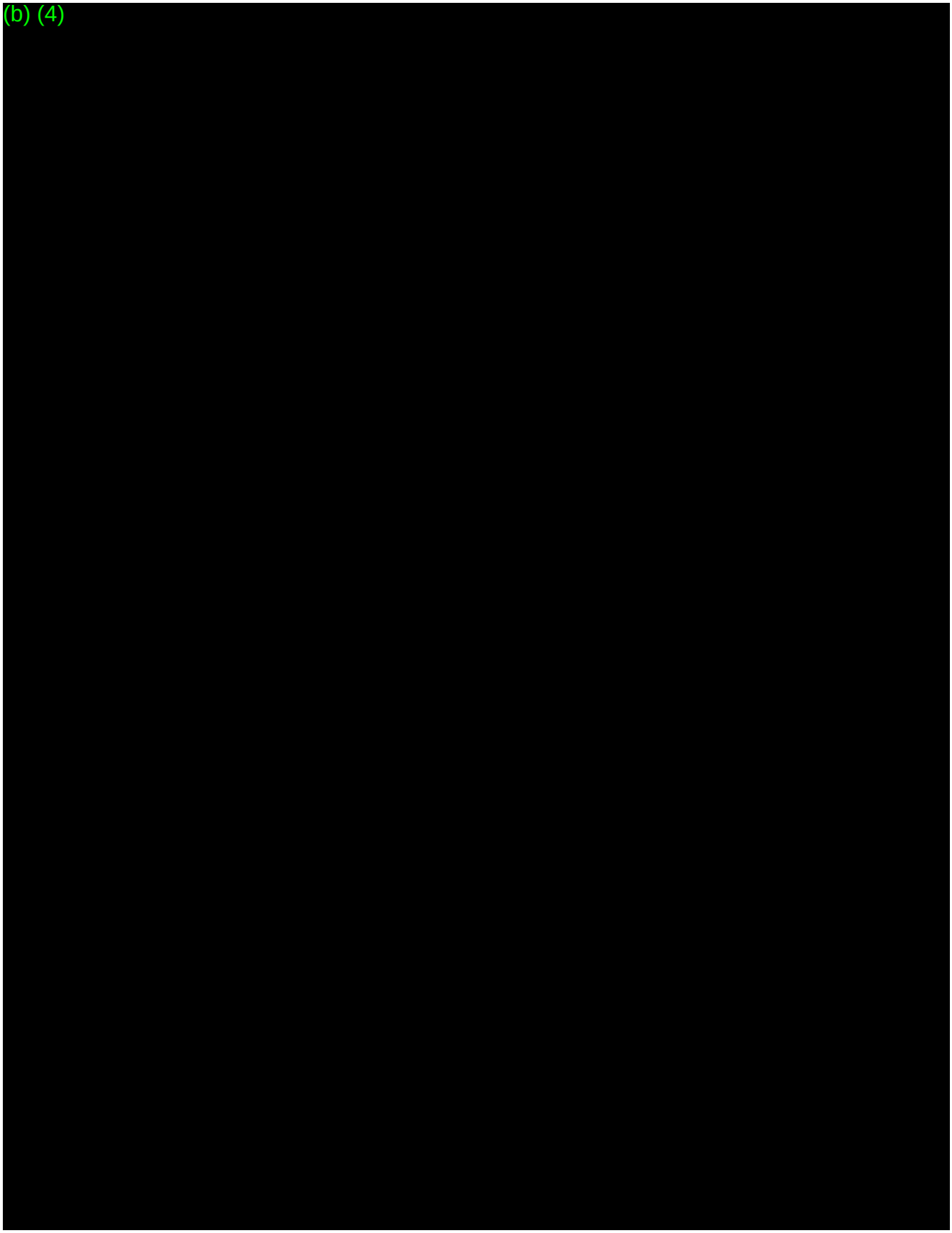

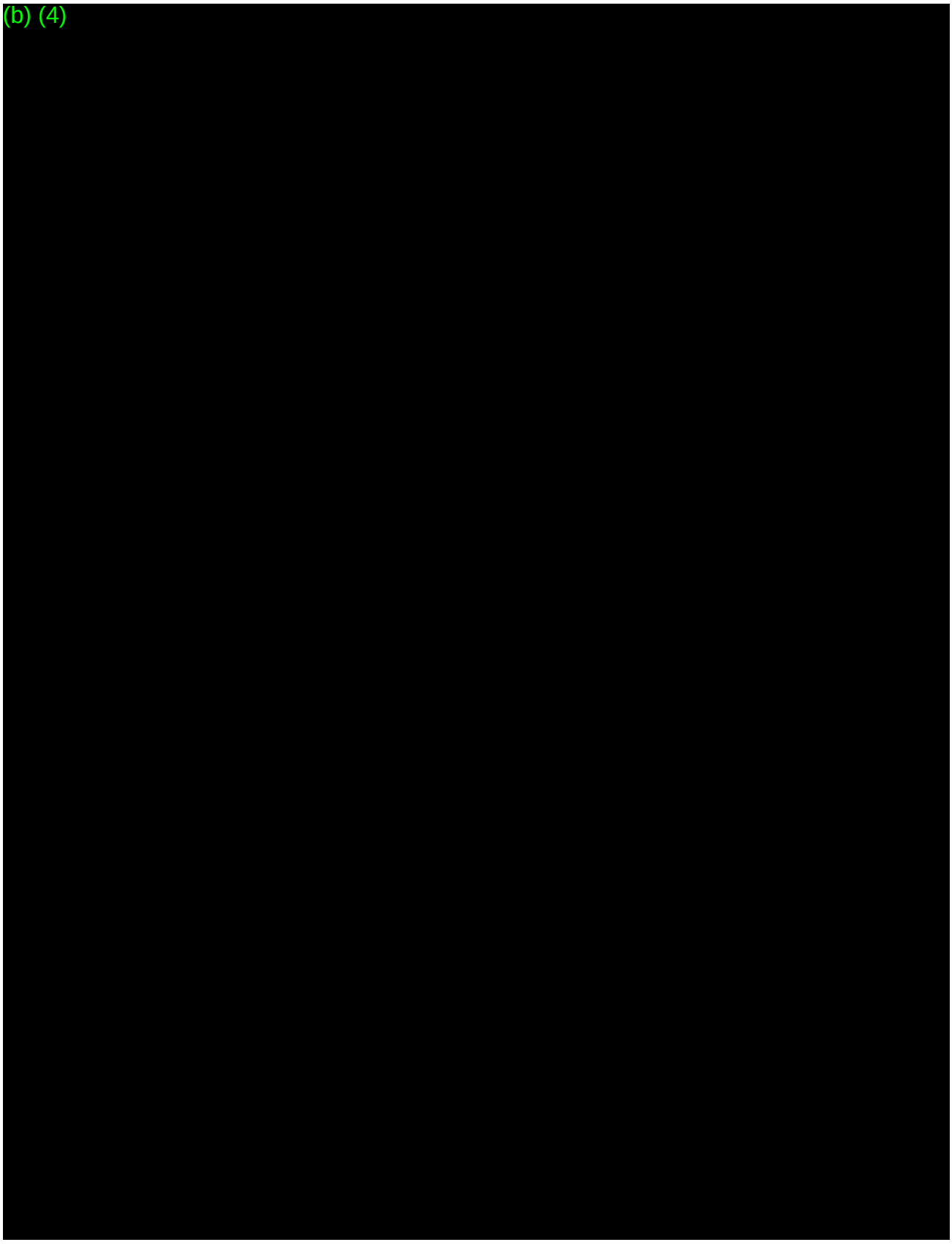

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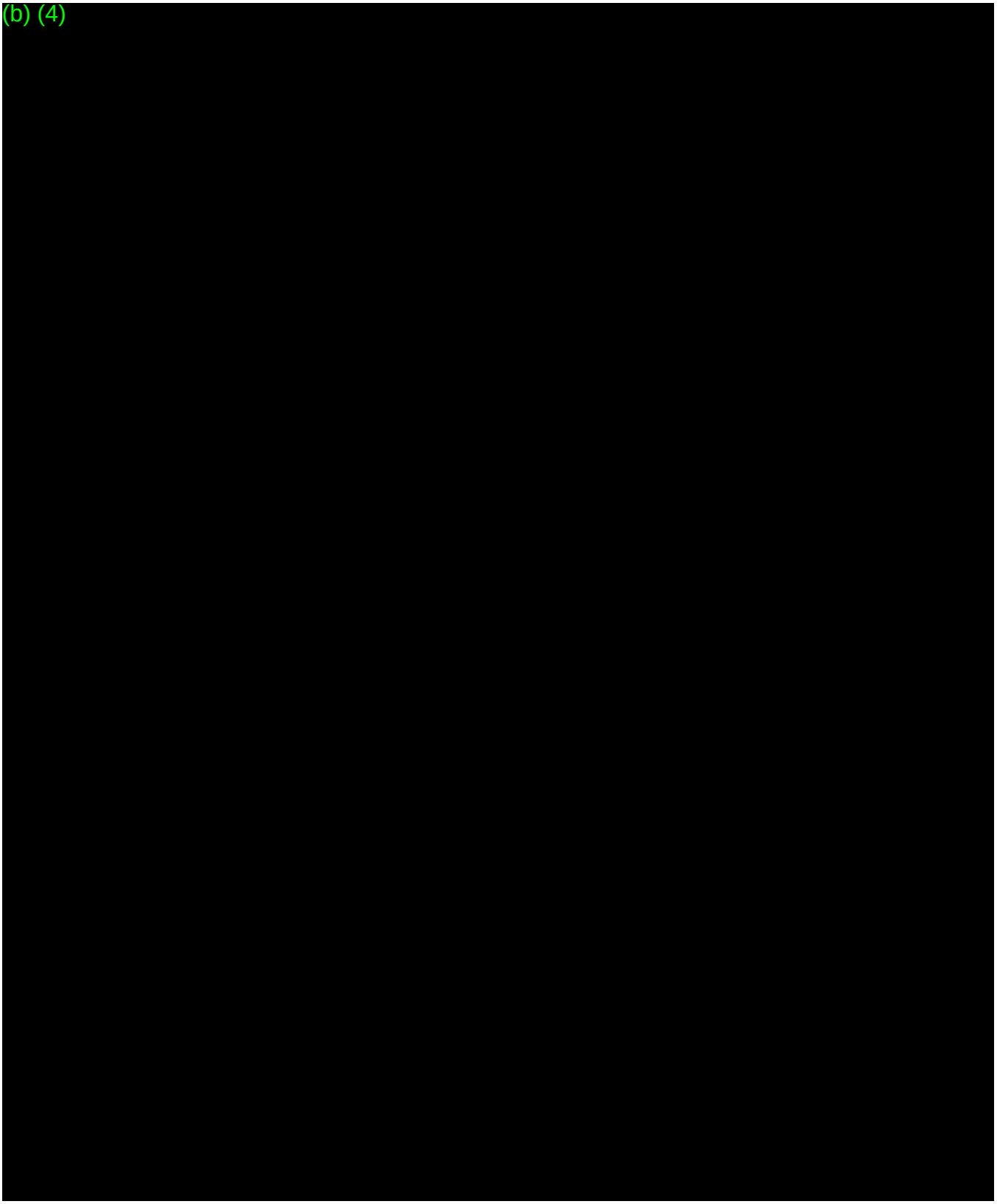

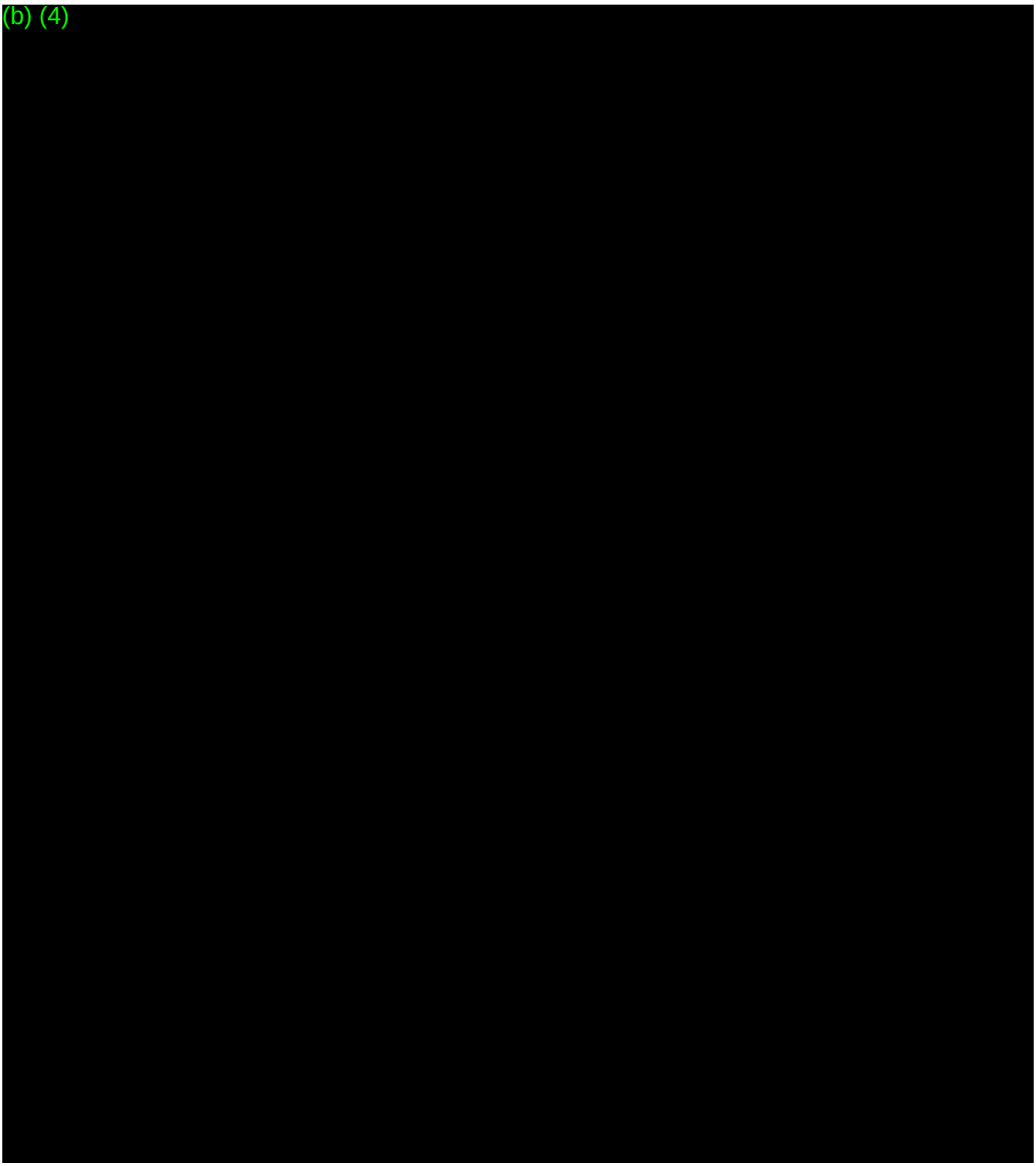

Software Performance and Functional Requirements

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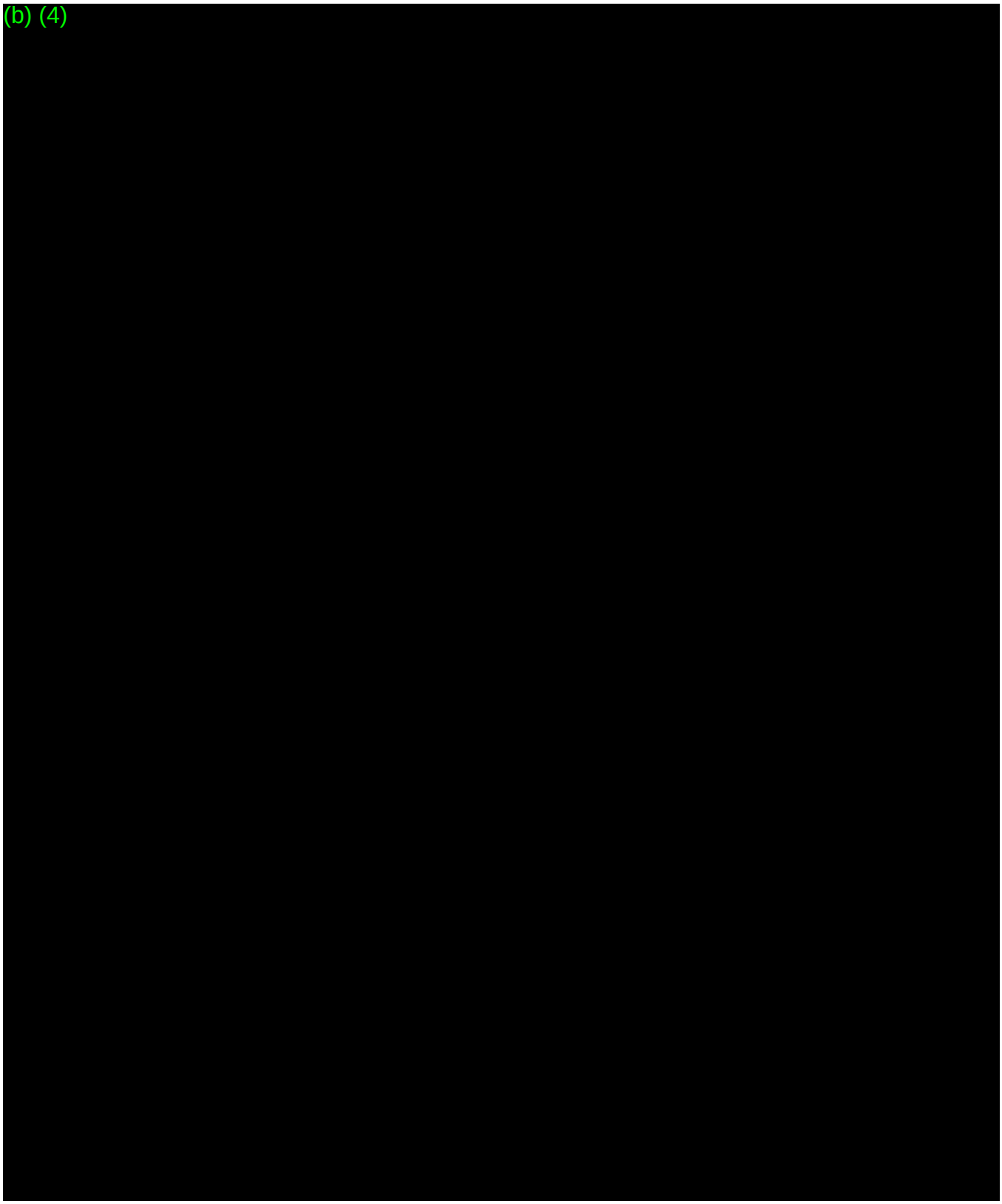

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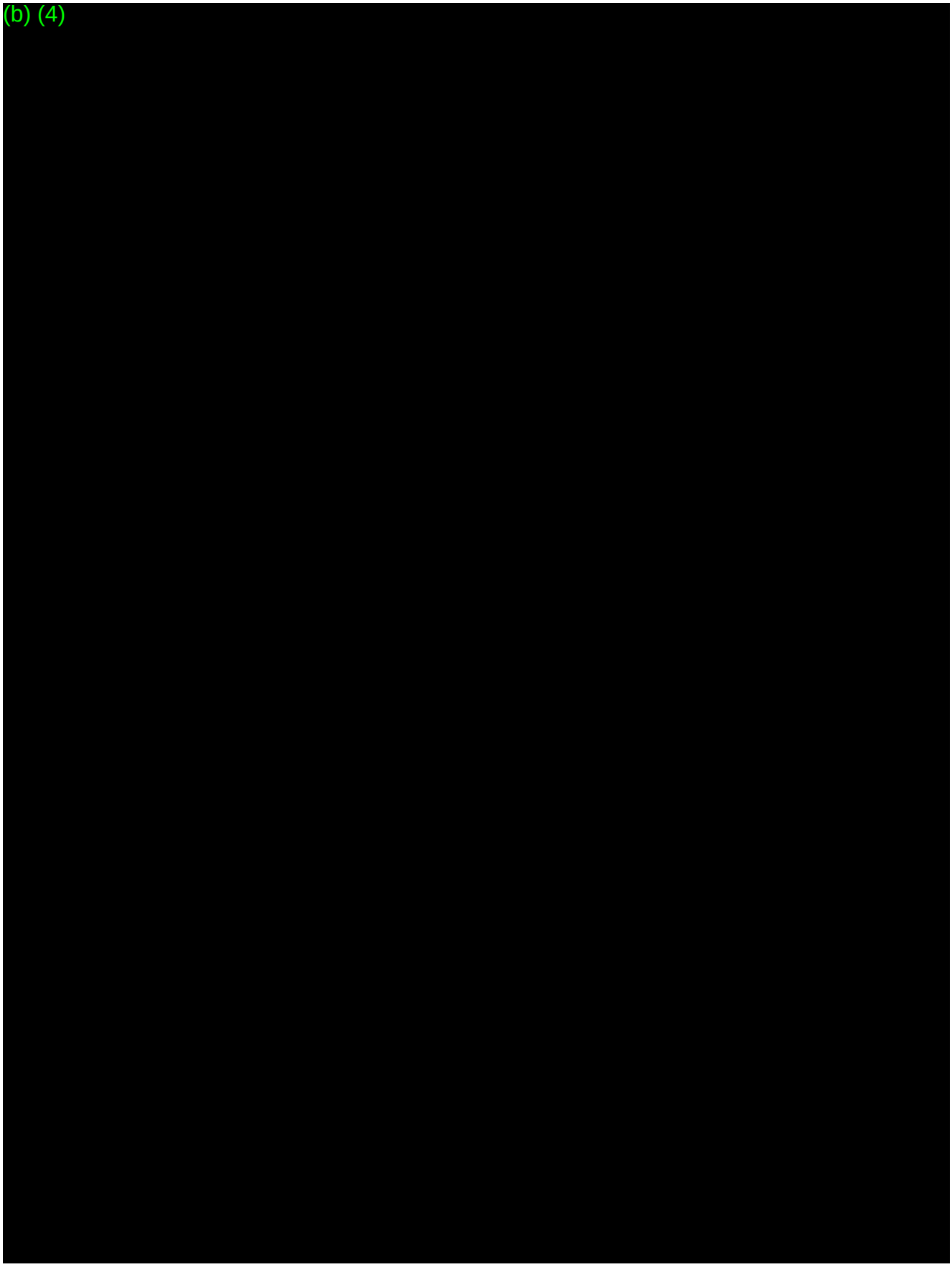

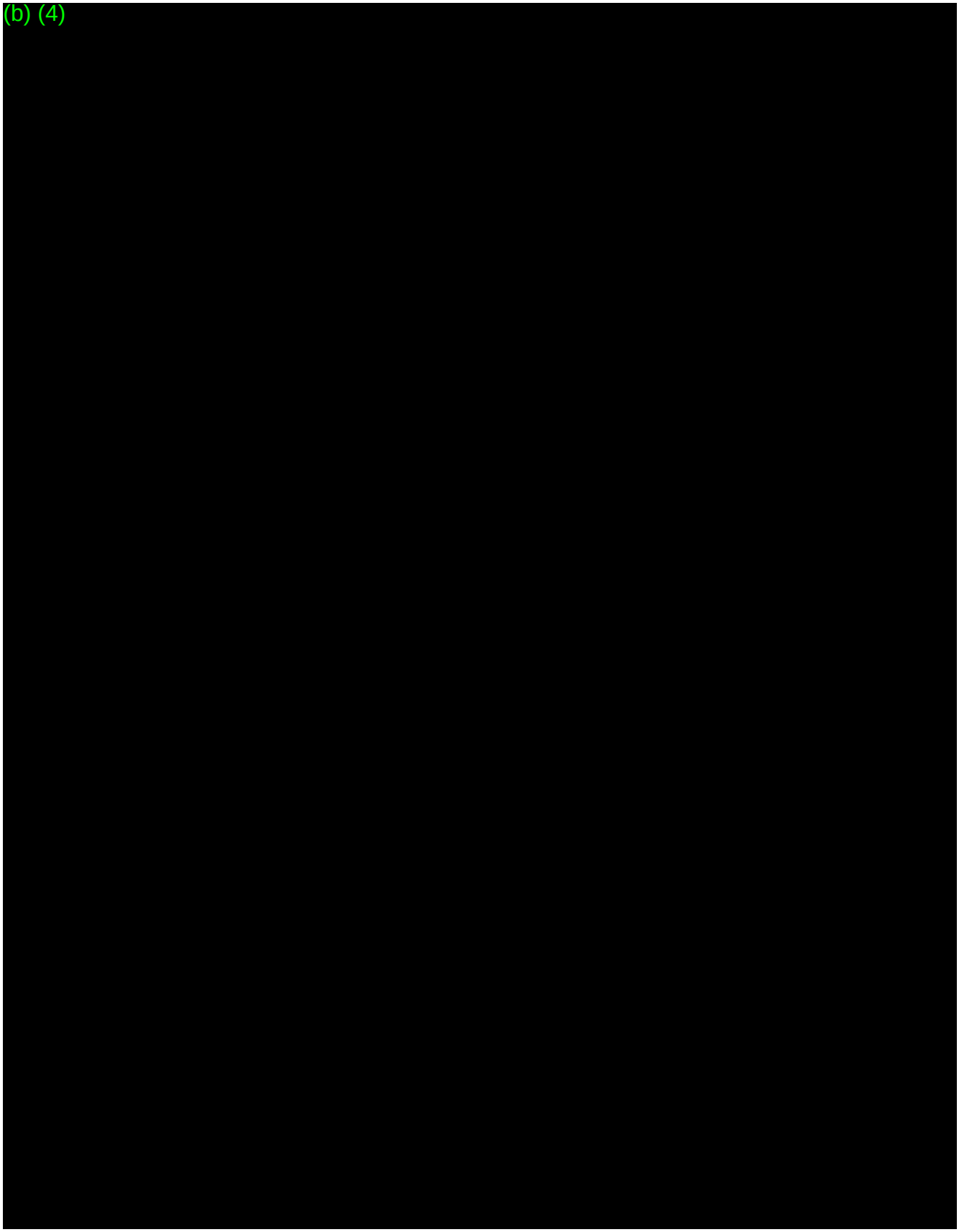

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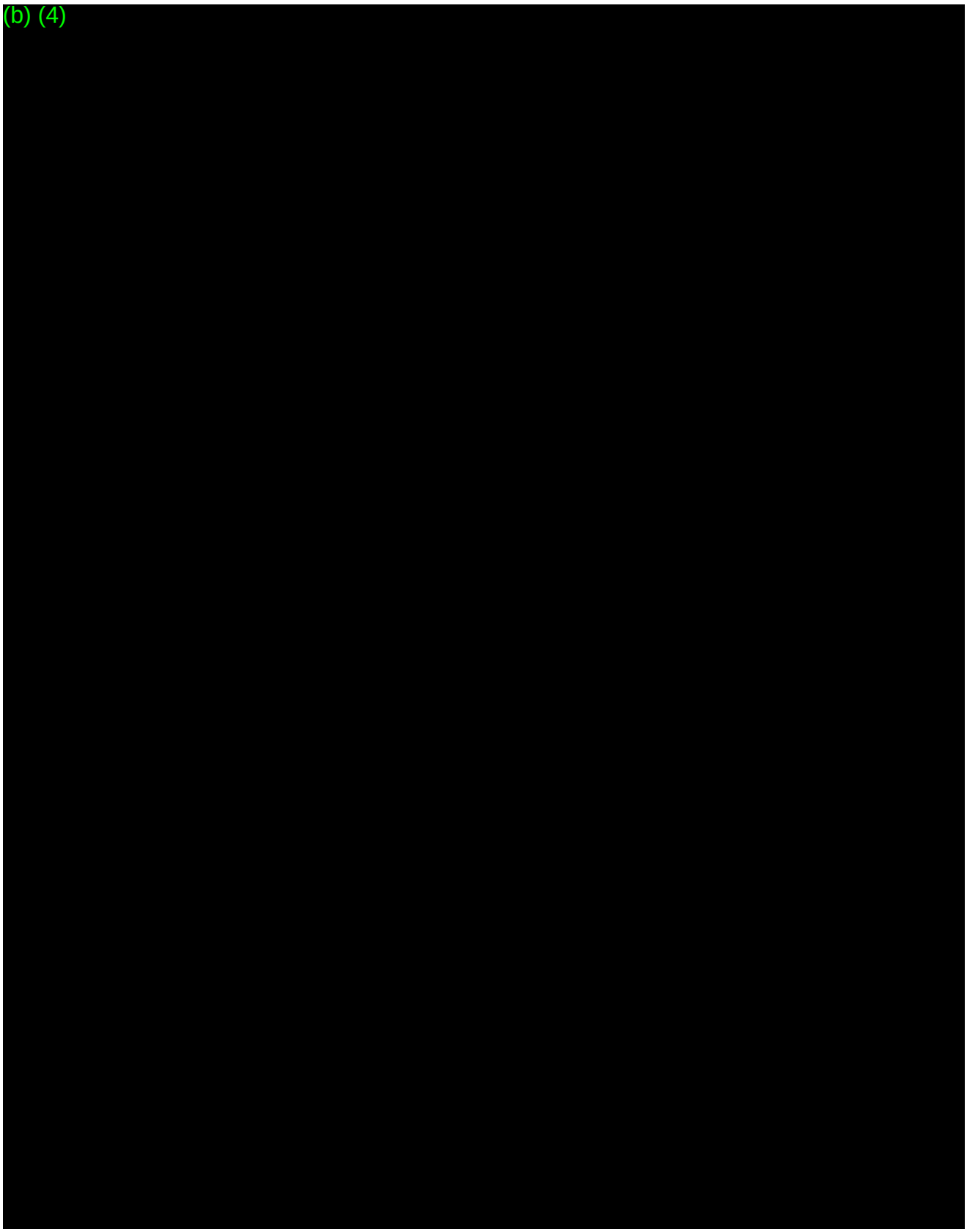
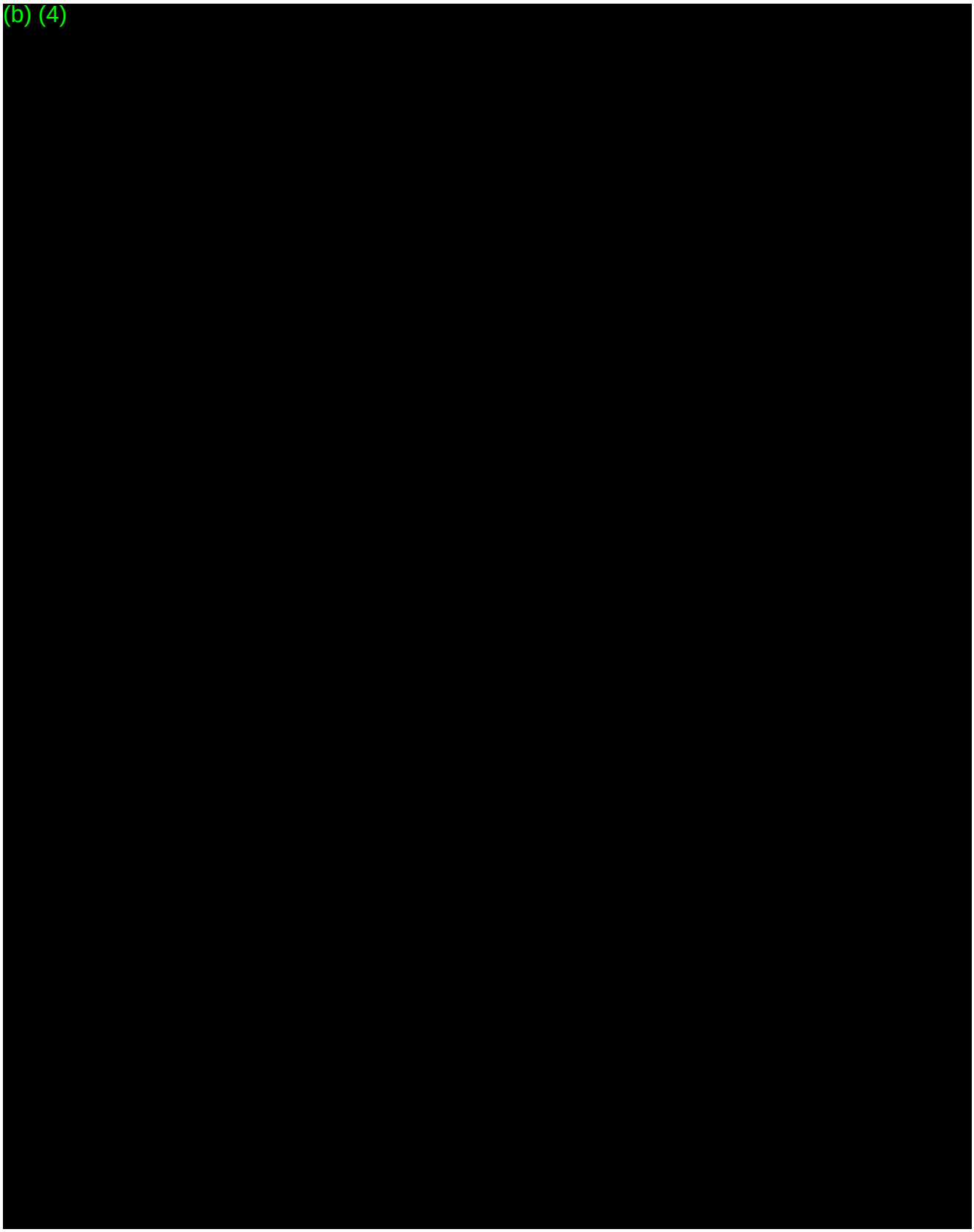
Appendix J: (b) (4) Design Specifications





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Appendix J: (b) (4) Design Specifications

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Appendix J: (b) (4) Design Specifications

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Appendix K Comparison of Key Platform Requirements with IEC 60601-2-47

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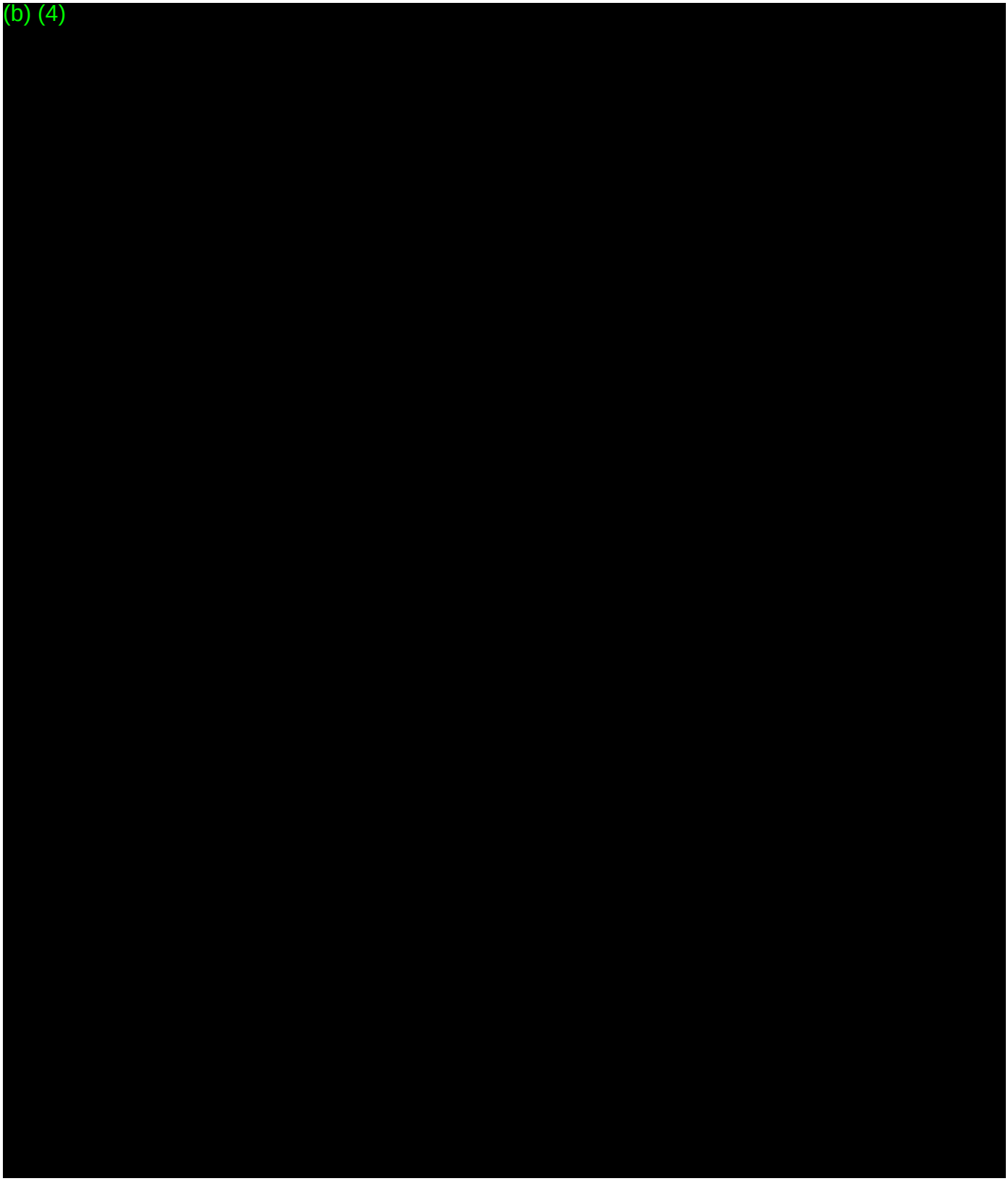

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Appendix L: (b) Algorithm Development

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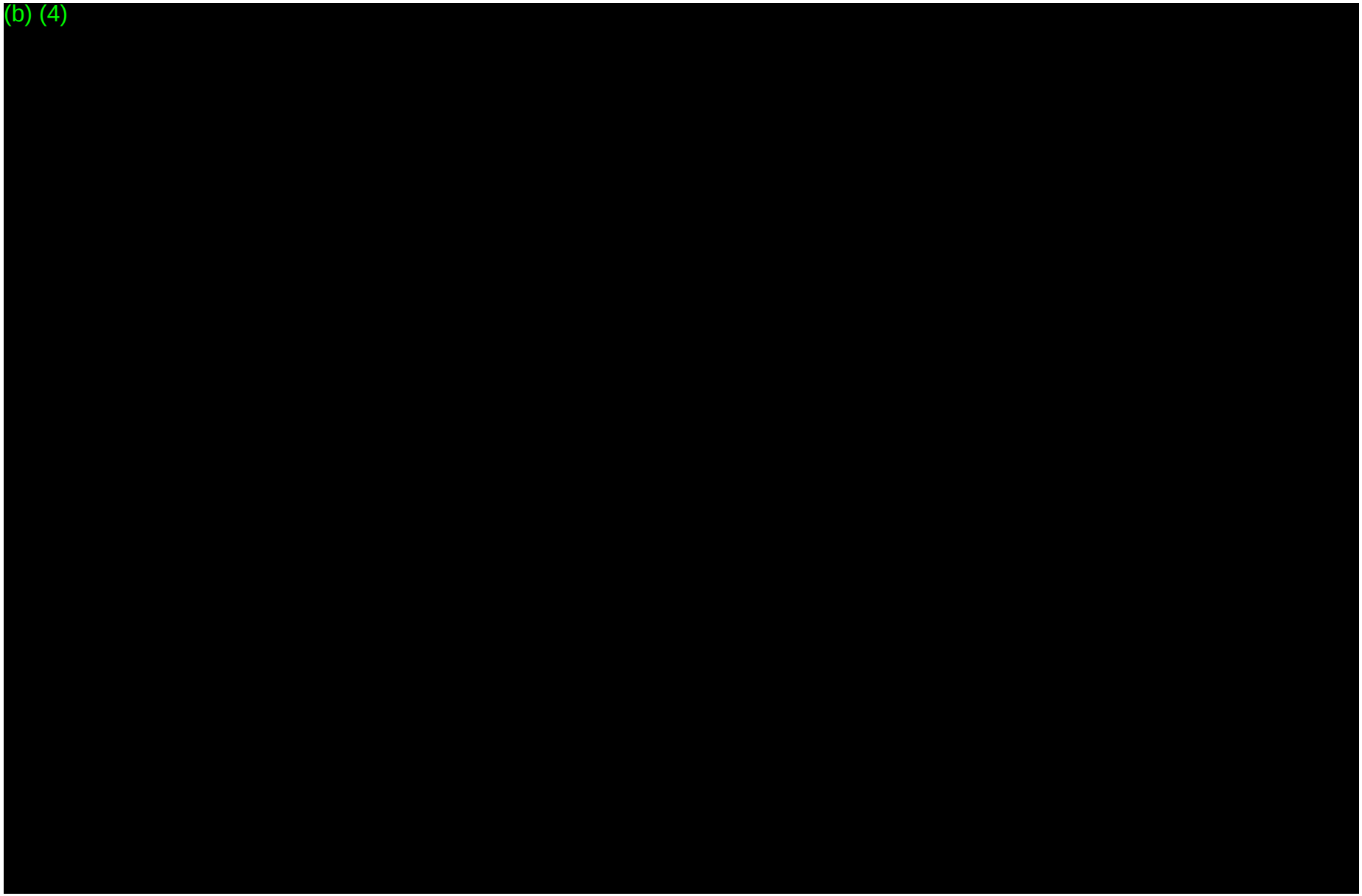
Appendix M: Cybersecurity

Appendix M: Cybersecurity



Appendix M: Cybersecurity

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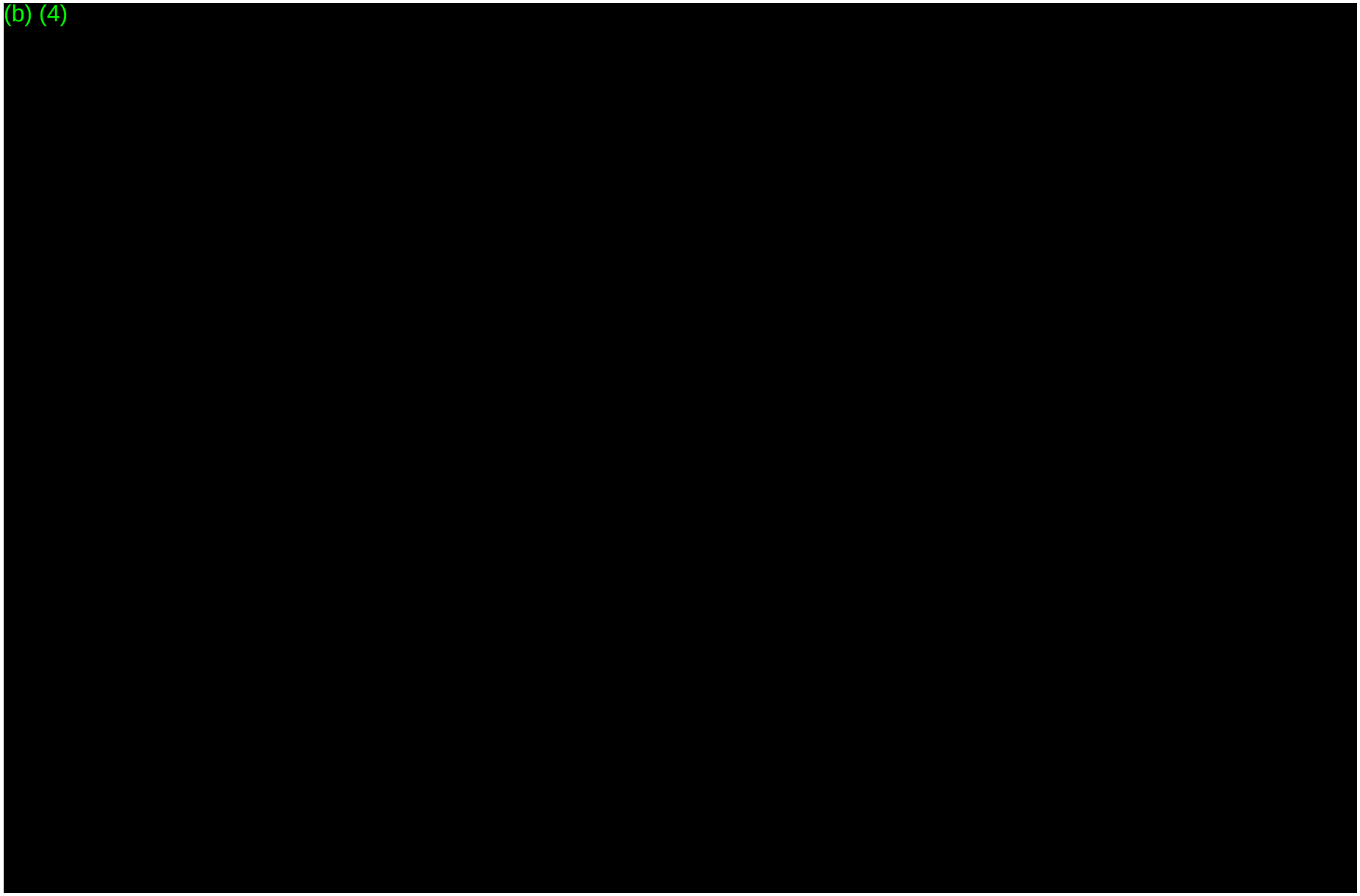

Appendix M: Cybersecurity

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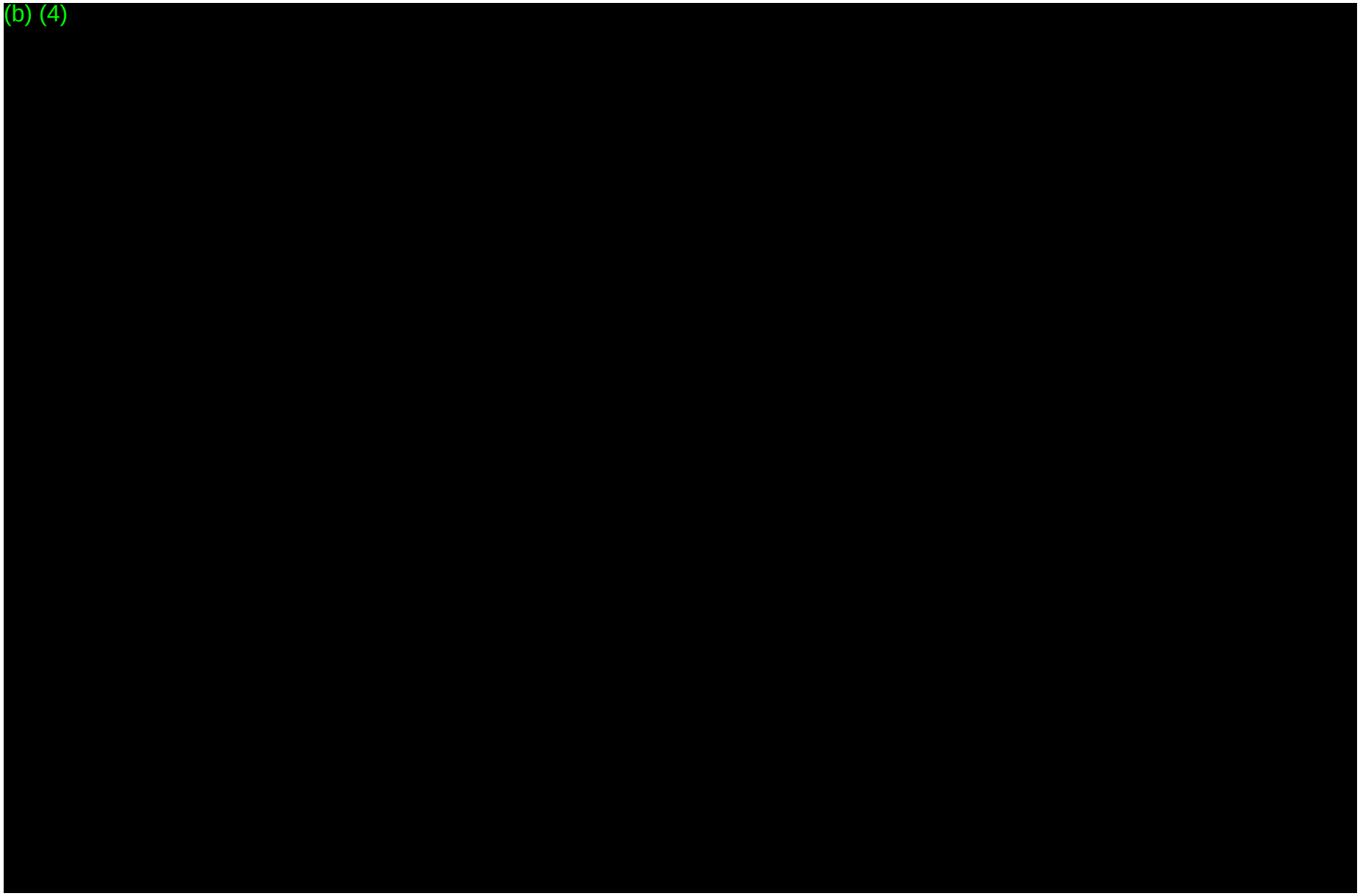

Appendix M: Cybersecurity

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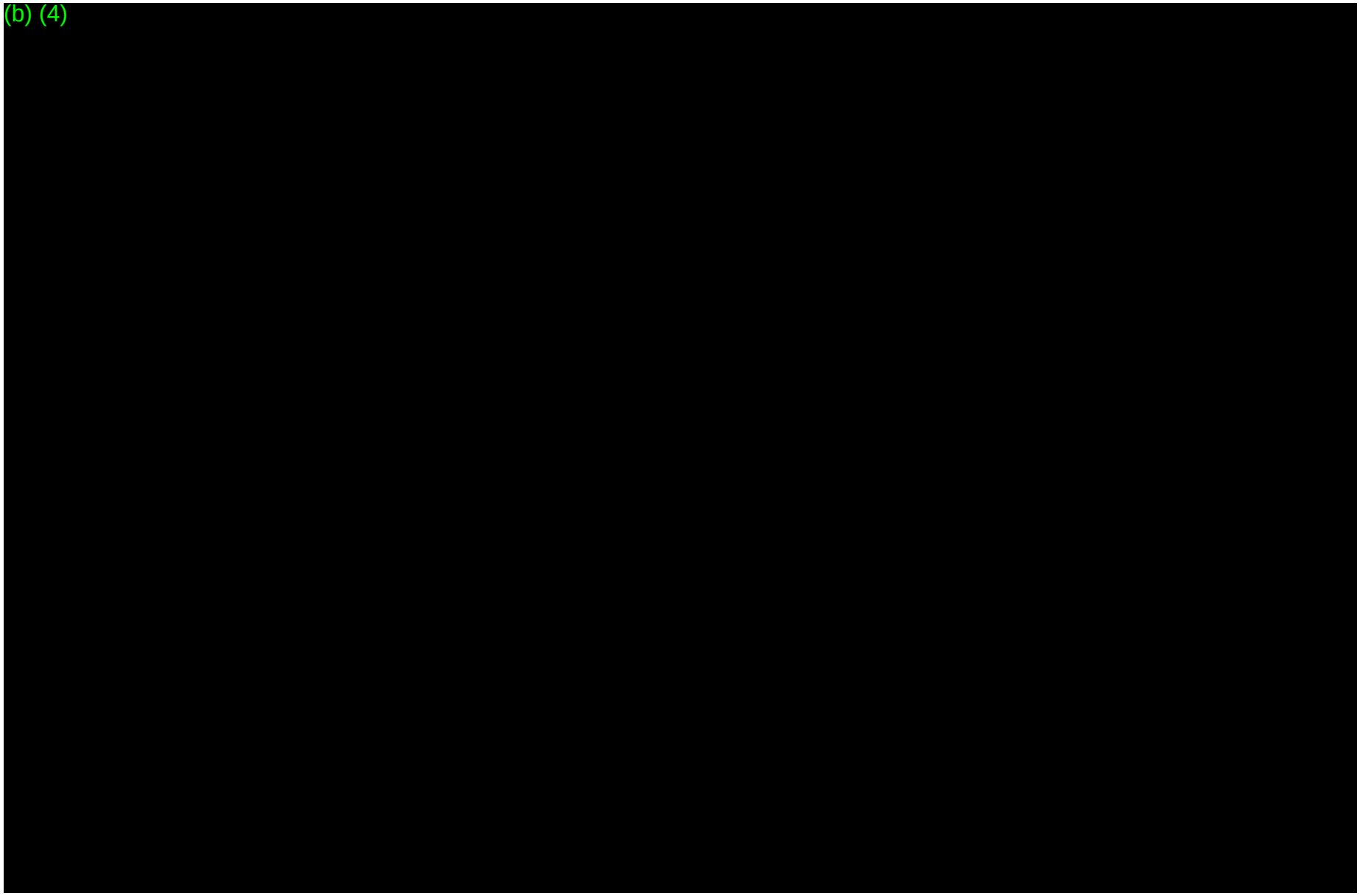

Appendix M: Cybersecurity

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Appendix M: Cybersecurity

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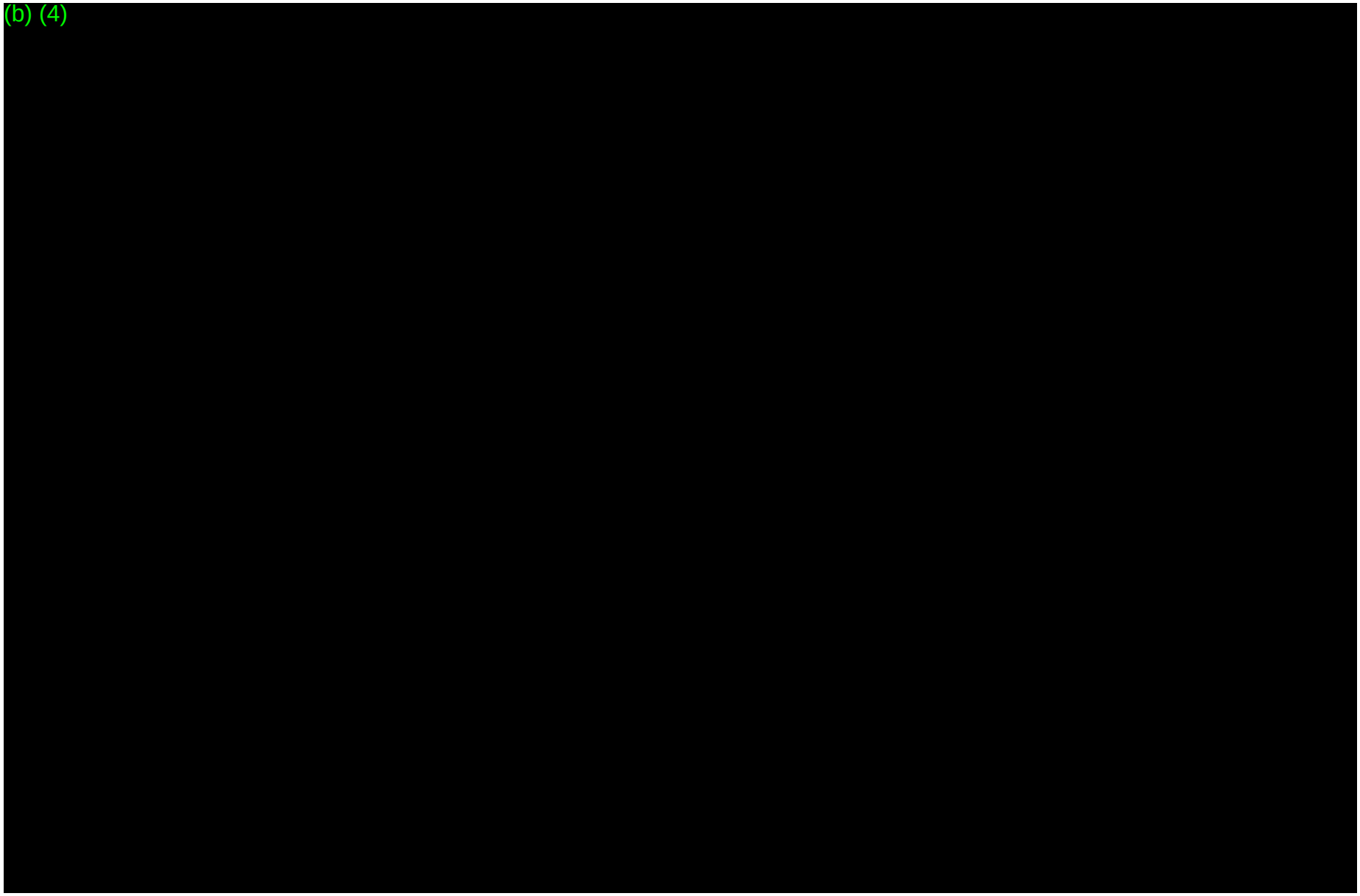

Appendix M: Cybersecurity

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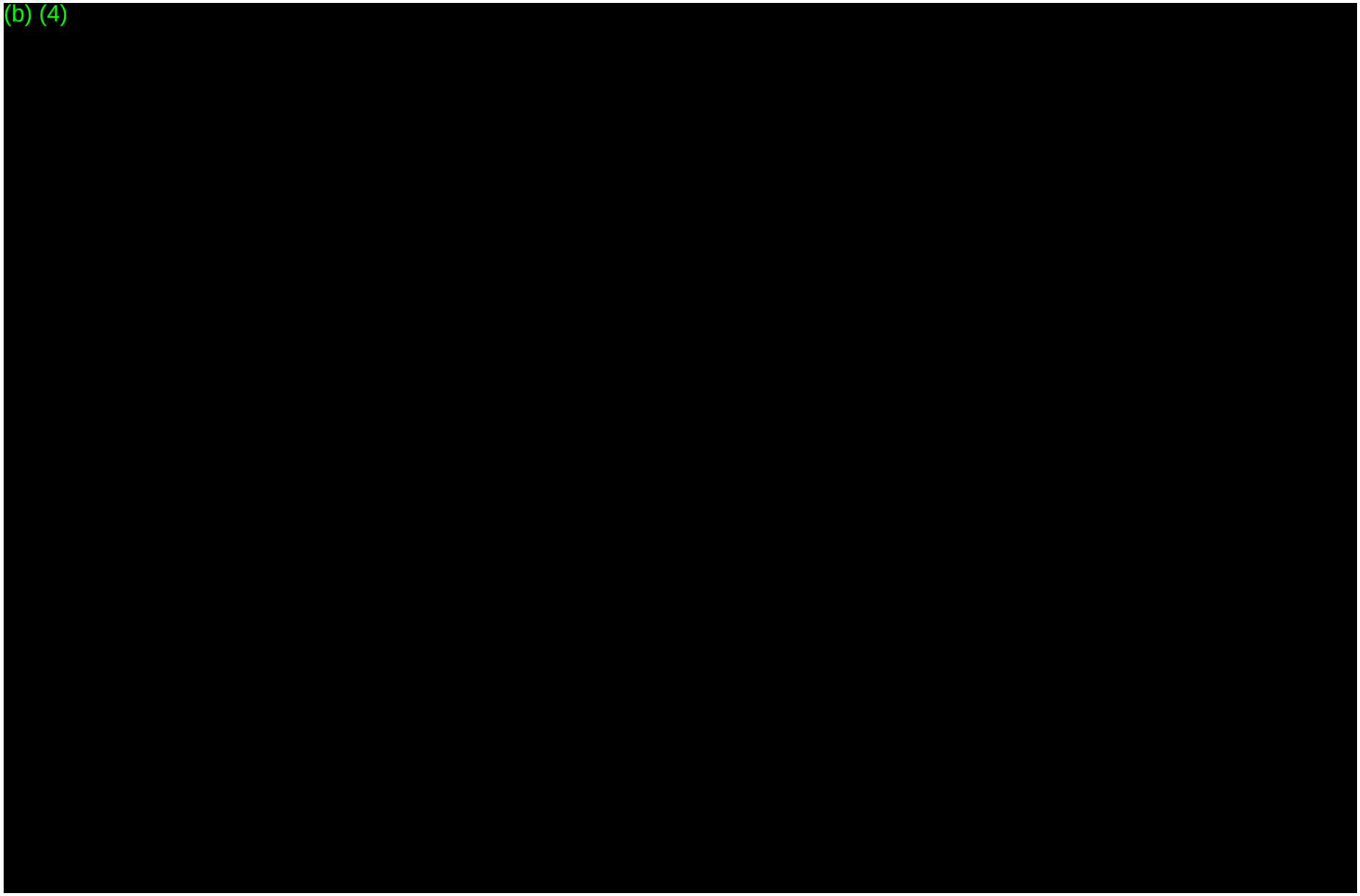

Appendix N: Off the Shelf Software

1. **What is it?** The (b) App uses iOS 12.1 and watchOS 5.1 (both manufactured by Apple). iOS and watchOS both allow applications to run on them. iOS contains the Health App and iPhone HealthKit, both of which are requirements for the (b) iPhone App. watchOS contains Watch HealthKit and Health Sensor Daemon, both of which are requirements for the (b) Watch App.

2. **What are the Computer System Specs for the OTS Software?** The specifications are included as part of the Software Requirements Specification provided in Appendix I.

3. **How will you assure appropriate actions are taken by the end user?** (b) (4) [redacted] iOS and watchOS are typically updated on a yearly basis (major releases), and "dot" releases (minor releases) occur throughout the year.

4. **What does the OTS Software do?** iOS and watchOS allow applications to run. iOS contains the Health App, which displays health information and iPhone HealthKit, which stores, manages, shares and sends heath and fitness data. watchOS contains Watch HealthKit, which sends data to iPhone HealthKit, and Health Sensor Daemon, which securely transmits requests and data.

5. **How do you know it works?** The (b) App runs on the operating system and uses features of the iOS and watchOS to fulfill various requirements, so this is inherently tested through the verification testing. The Verification Test Protocol is included in Appendix P. Results will also be included in the final de novo submission.

6. **How will you control the OTS SW?** Once the iOS kernel has started, it controls which user processes and apps can be run. To ensure that all apps come from a known and approved source and haven't been tampered with, iOS requires that all executable code be signed using an Apple-issued certificate. Third-party apps must be validated and signed using an Apple-issued certificate. Mandatory code signing extends the concept of chain of trust from the OS to apps, and prevents third-party apps from loading unsigned code resources or using self-modifying code.

   In order to develop and install apps on iOS devices, developers must register with Apple and join the Apple Developer Program in order to be able to sign apps and submit them to the App Store for distribution. As a result, all apps in the App Store have been submitted by an identifiable person or organization, serving as a deterrent to the creation of malicious apps. They have also been reviewed by Apple to ensure they operate as described and do not contain obvious bugs or other problems.

Appendix N: Off the Shelf Software

Unlike other mobile platforms, iOS does not allow users to install potentially malicious unsigned apps from websites, or run untrusted code. At runtime, code signature checks of all executable memory pages are made as they are loaded to ensure that an app has not been modified since it was installed or last updated.

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Appendix P: Verification (QA) Test Report

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Appendix P: Verification (QA) Test Report

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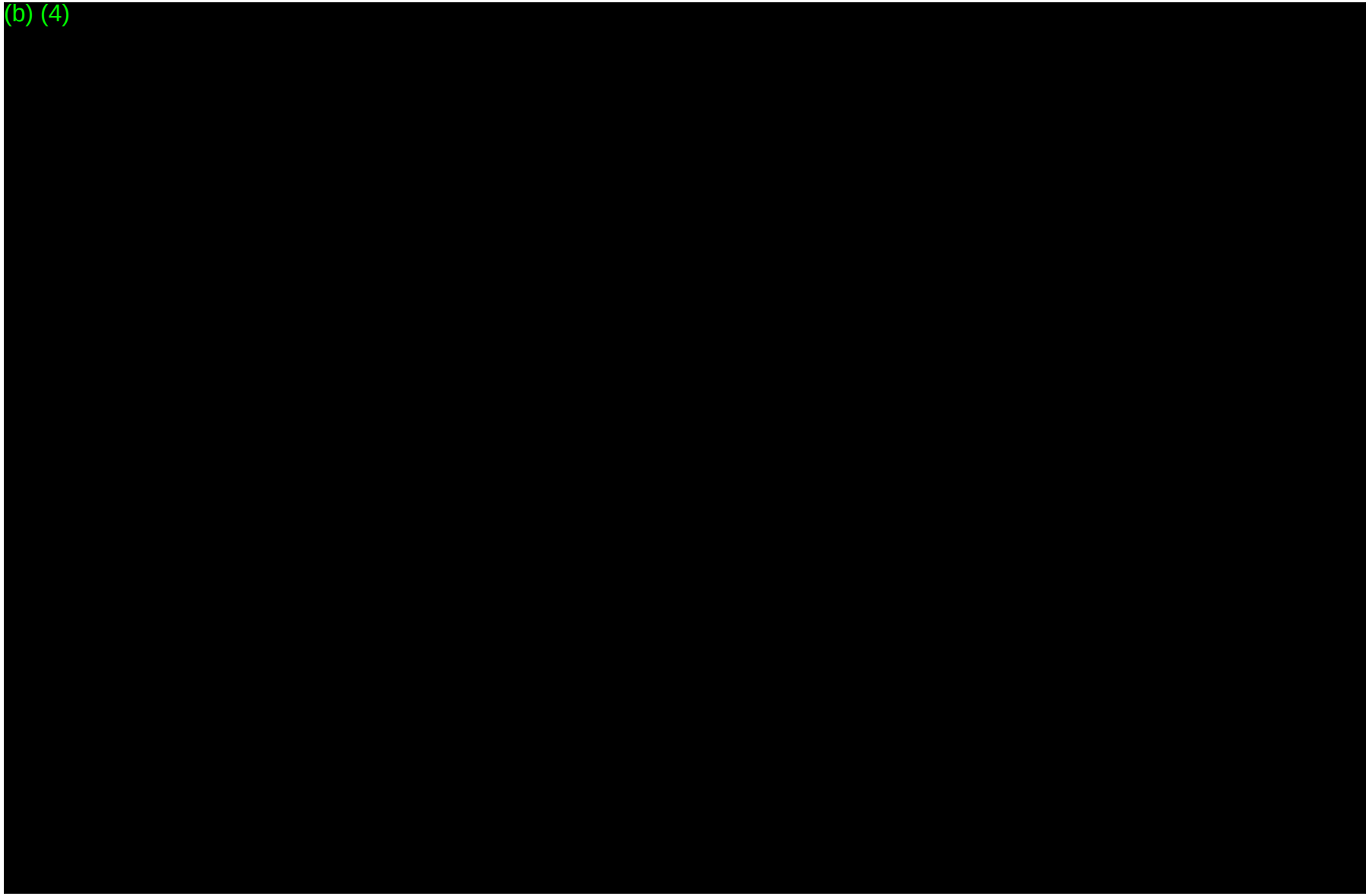
Appendix Q: Traceability Matrix (updated)



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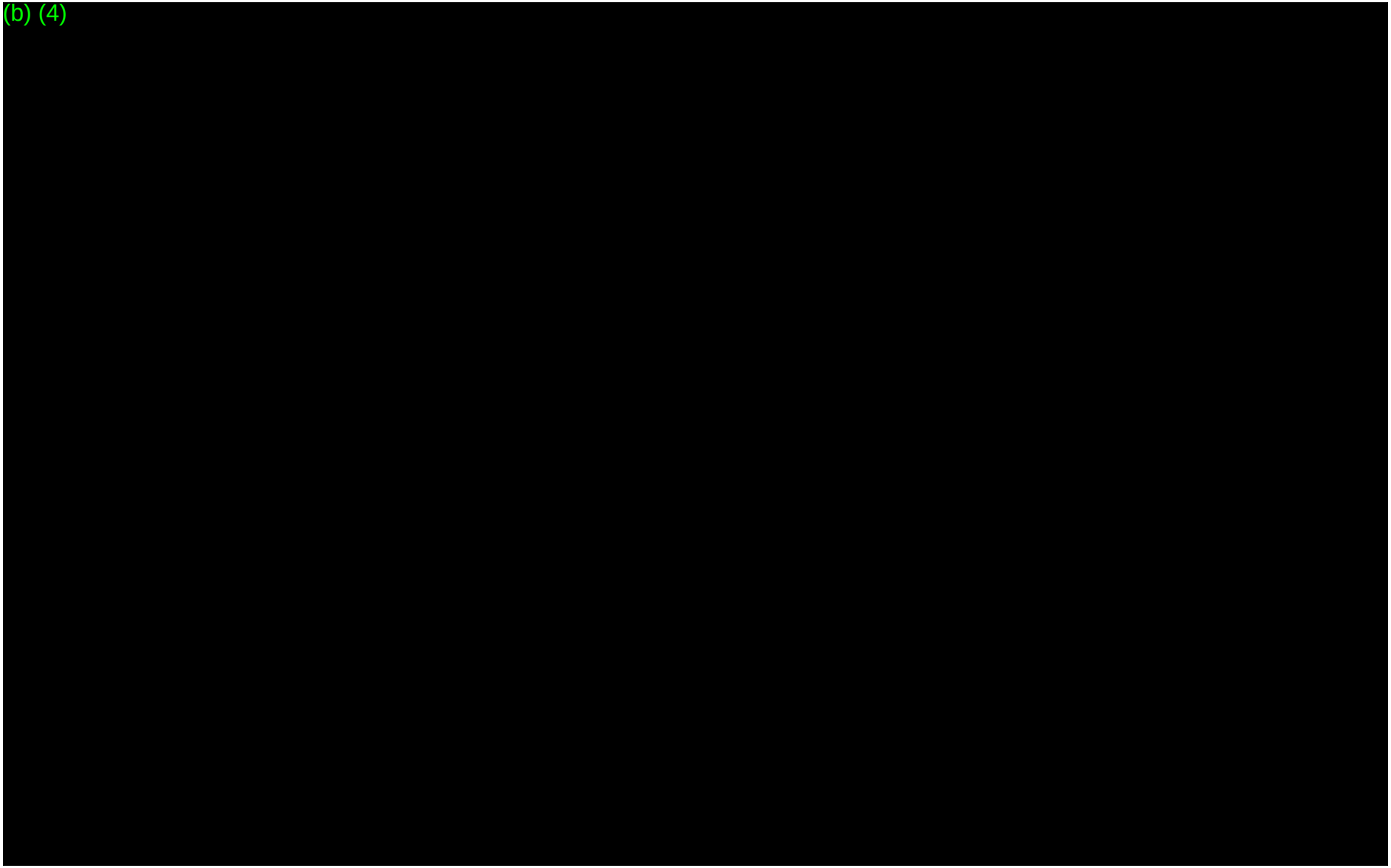

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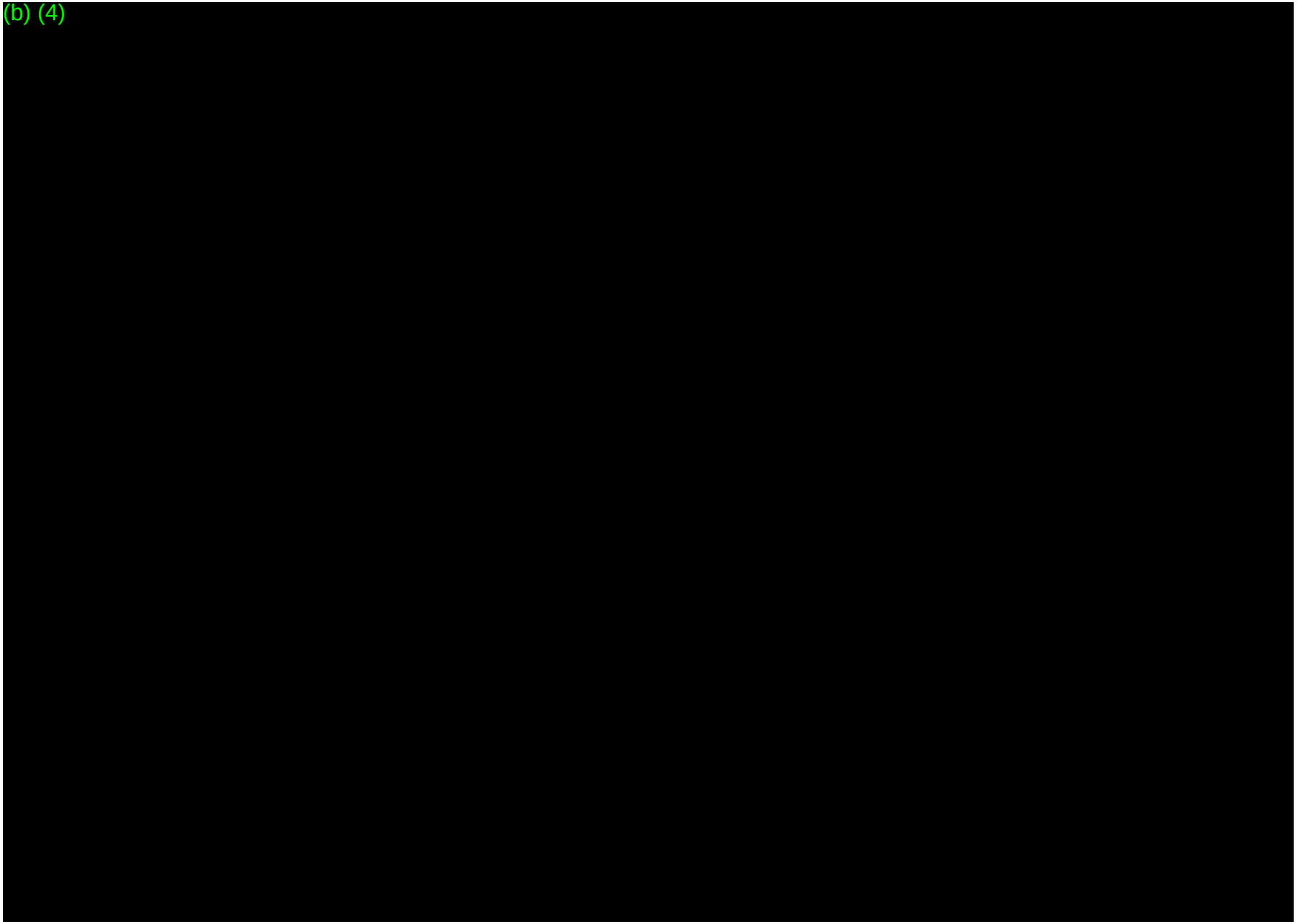

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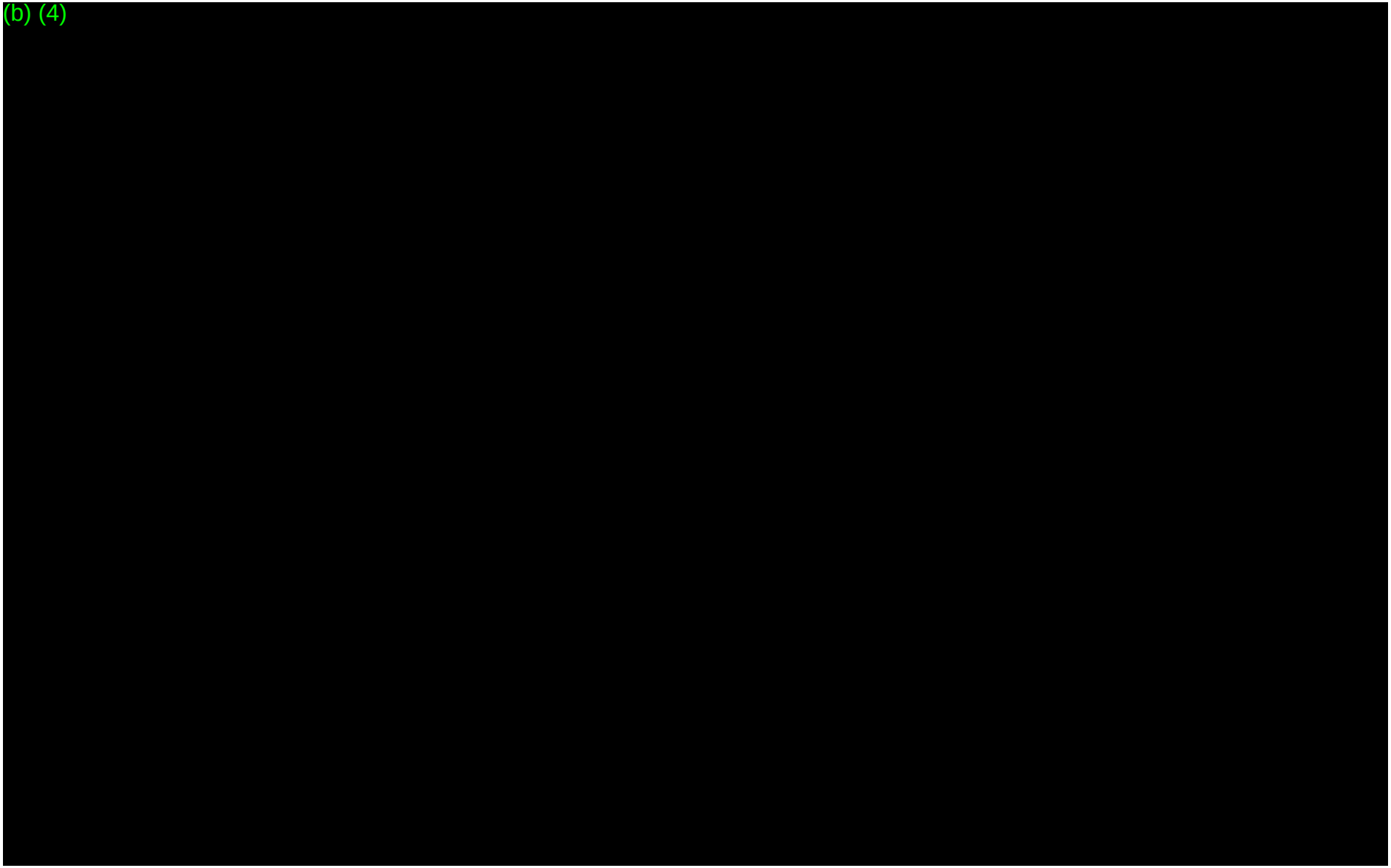

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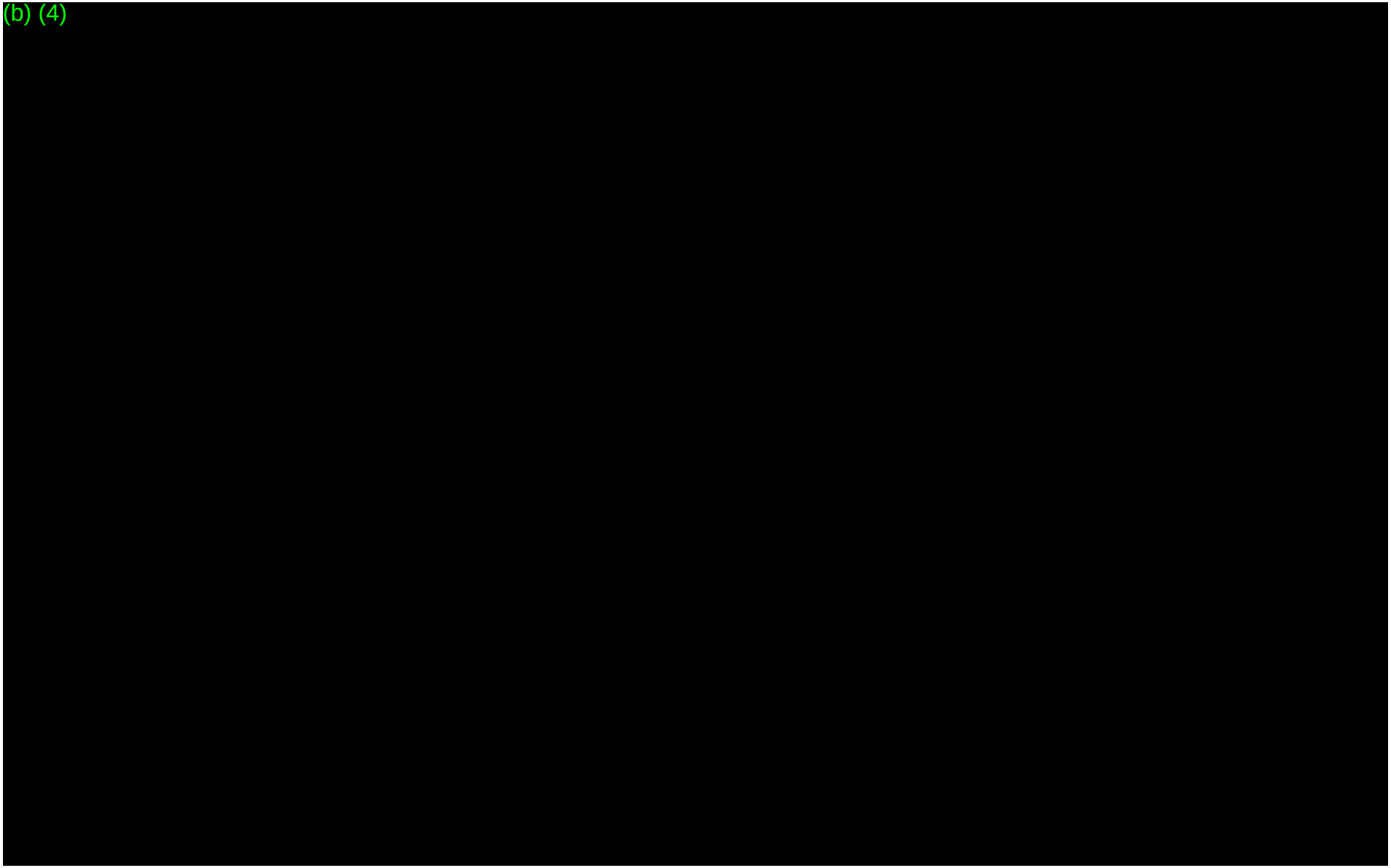

Appendix Q: Traceability Matrix (updated)

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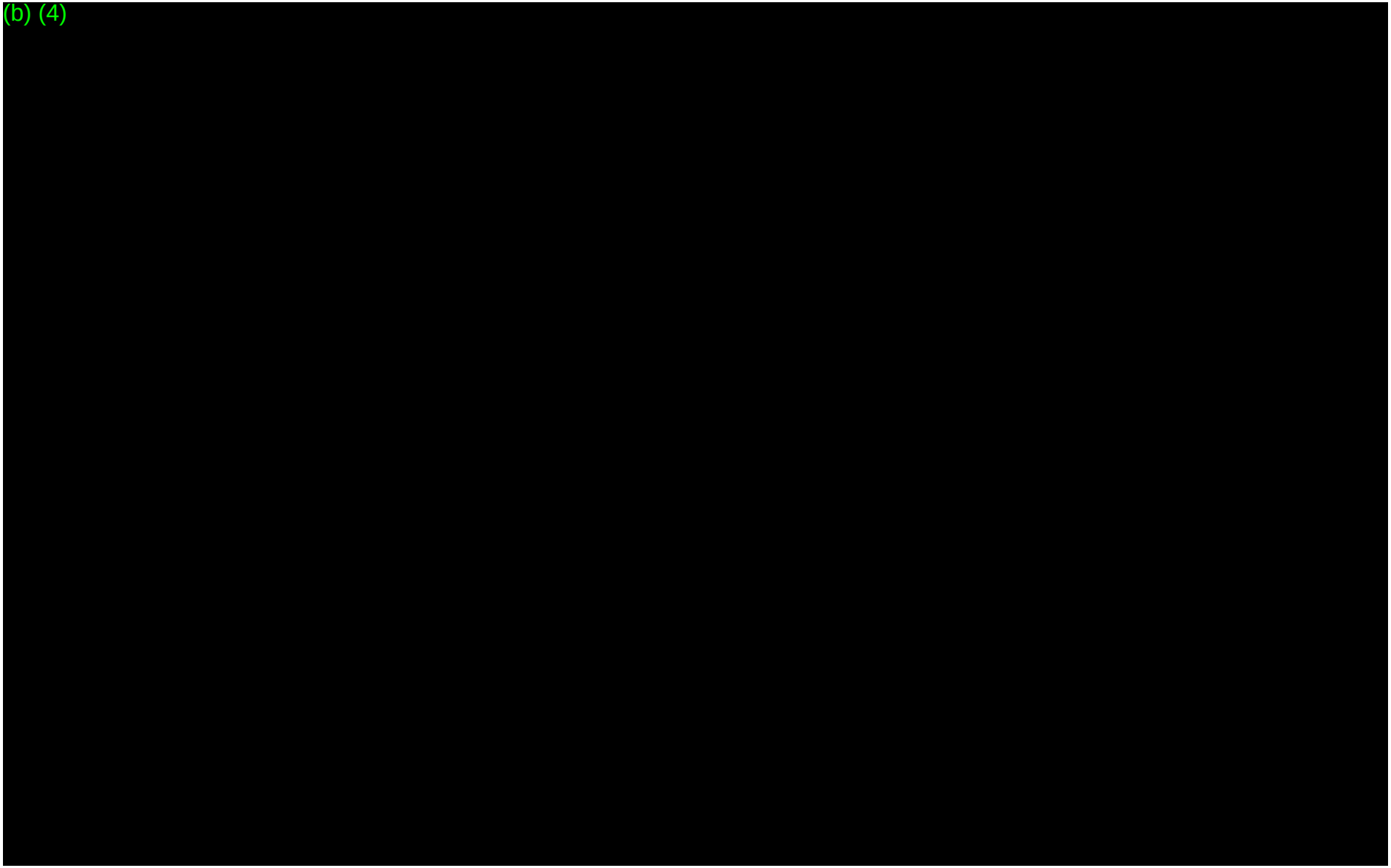
Appendix Q: Traceability Matrix (updated)



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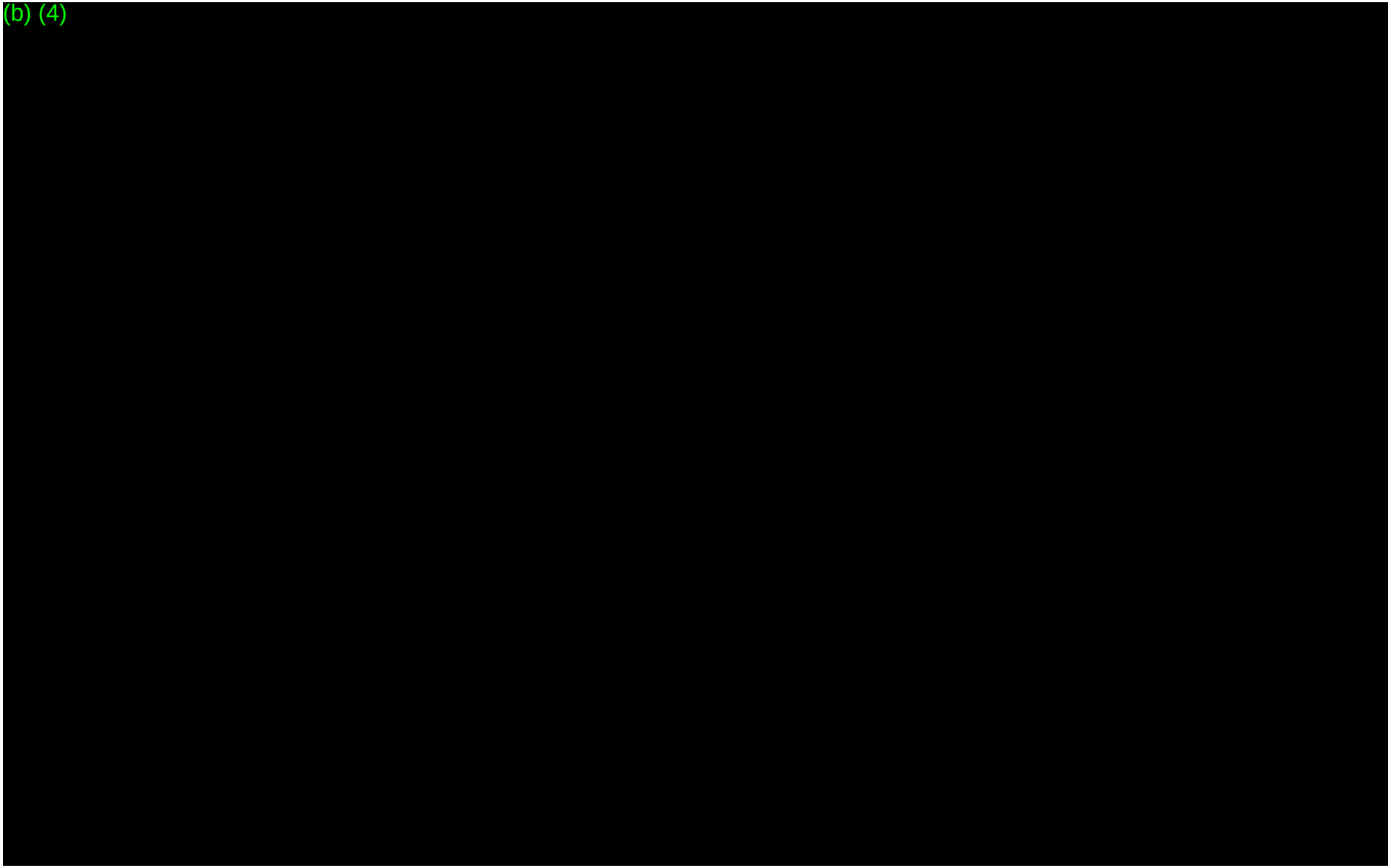

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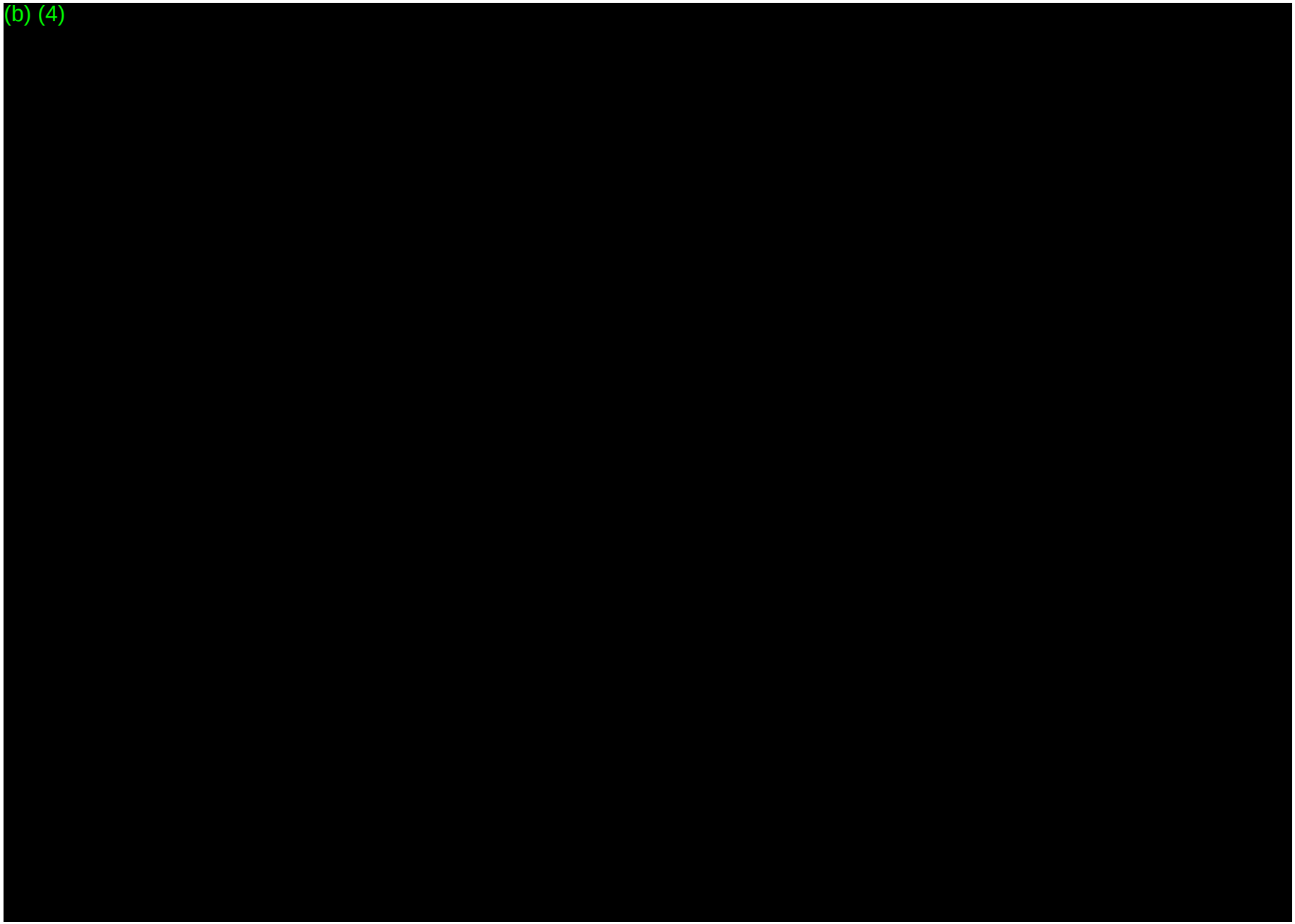

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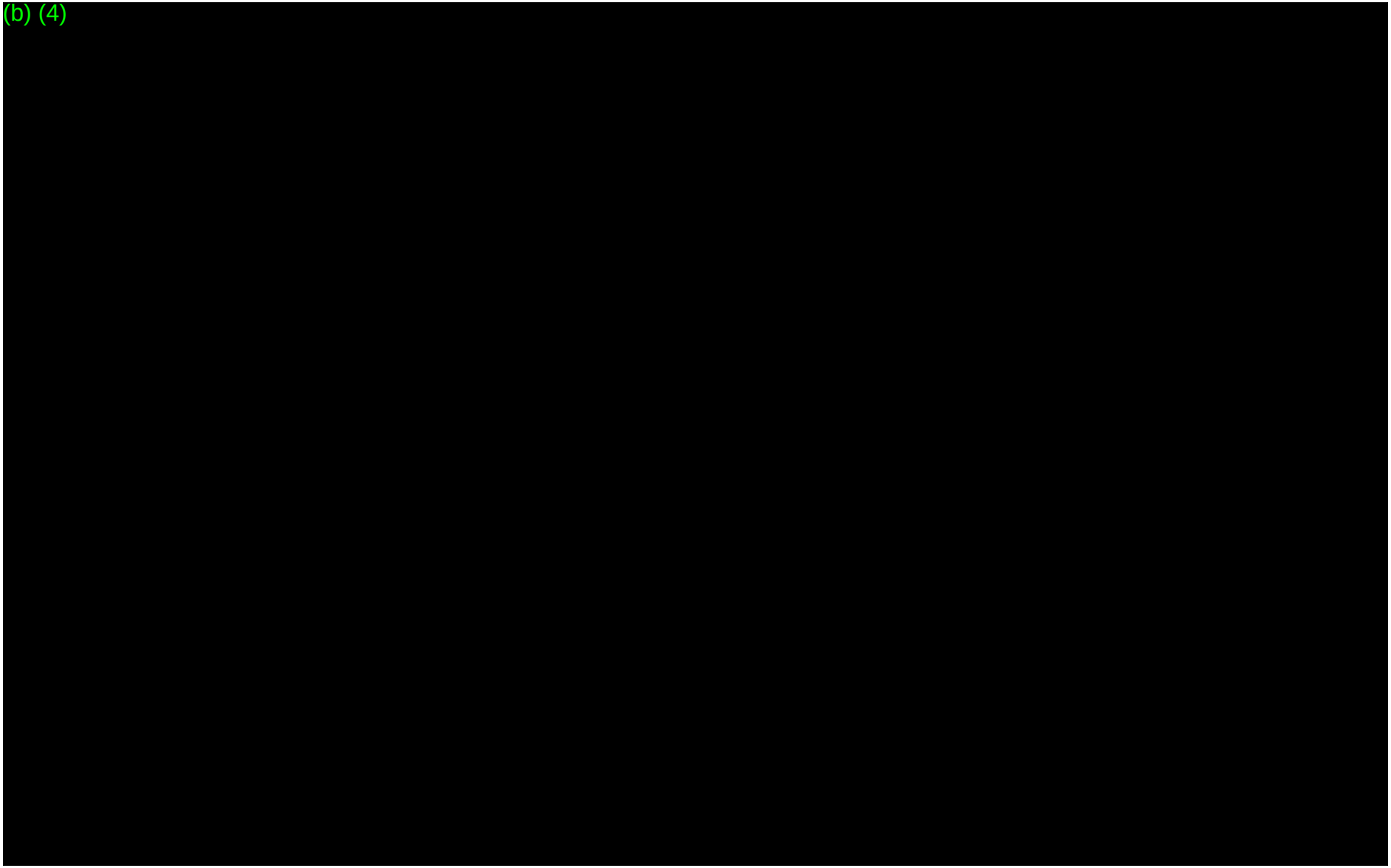

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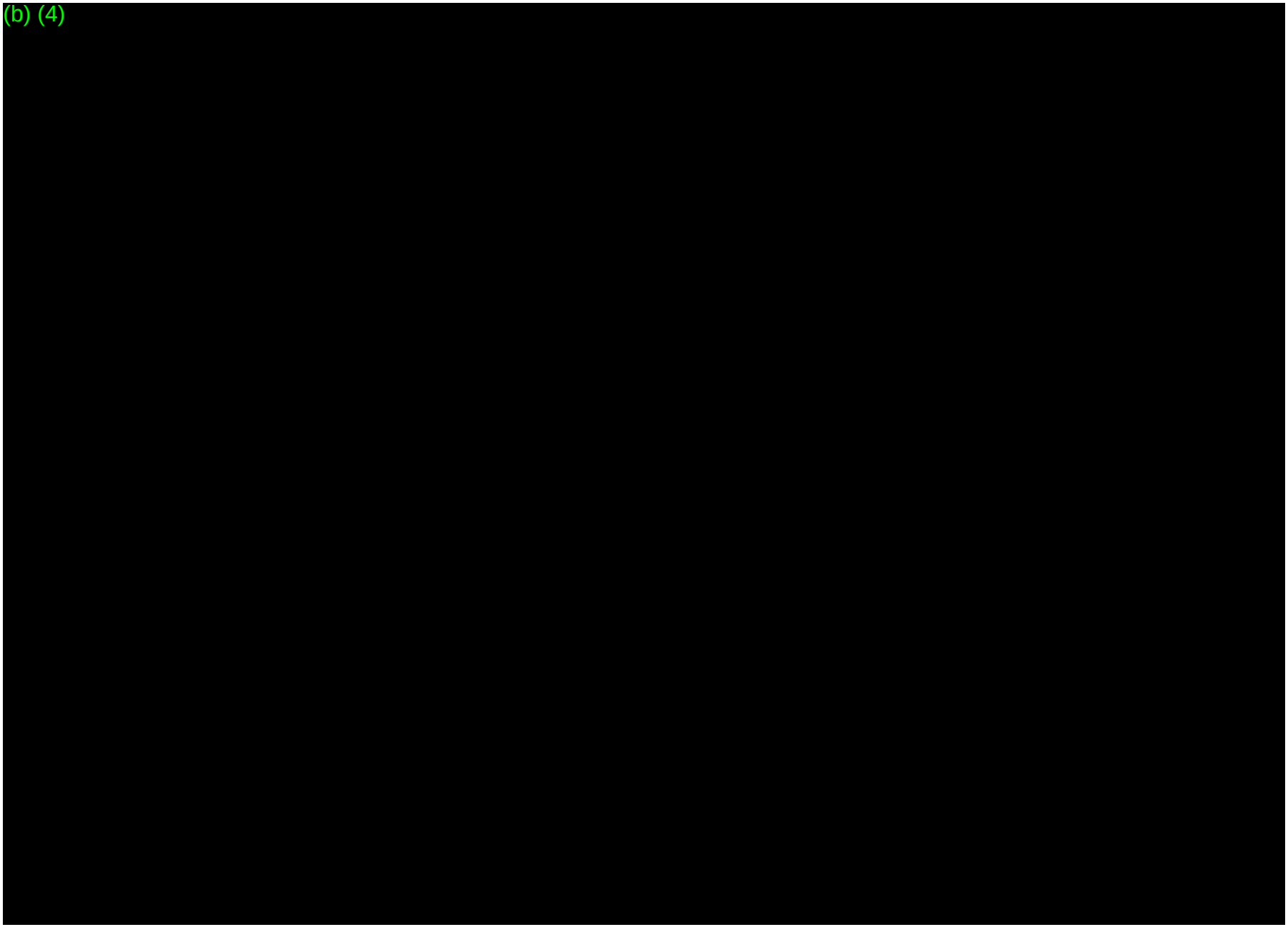

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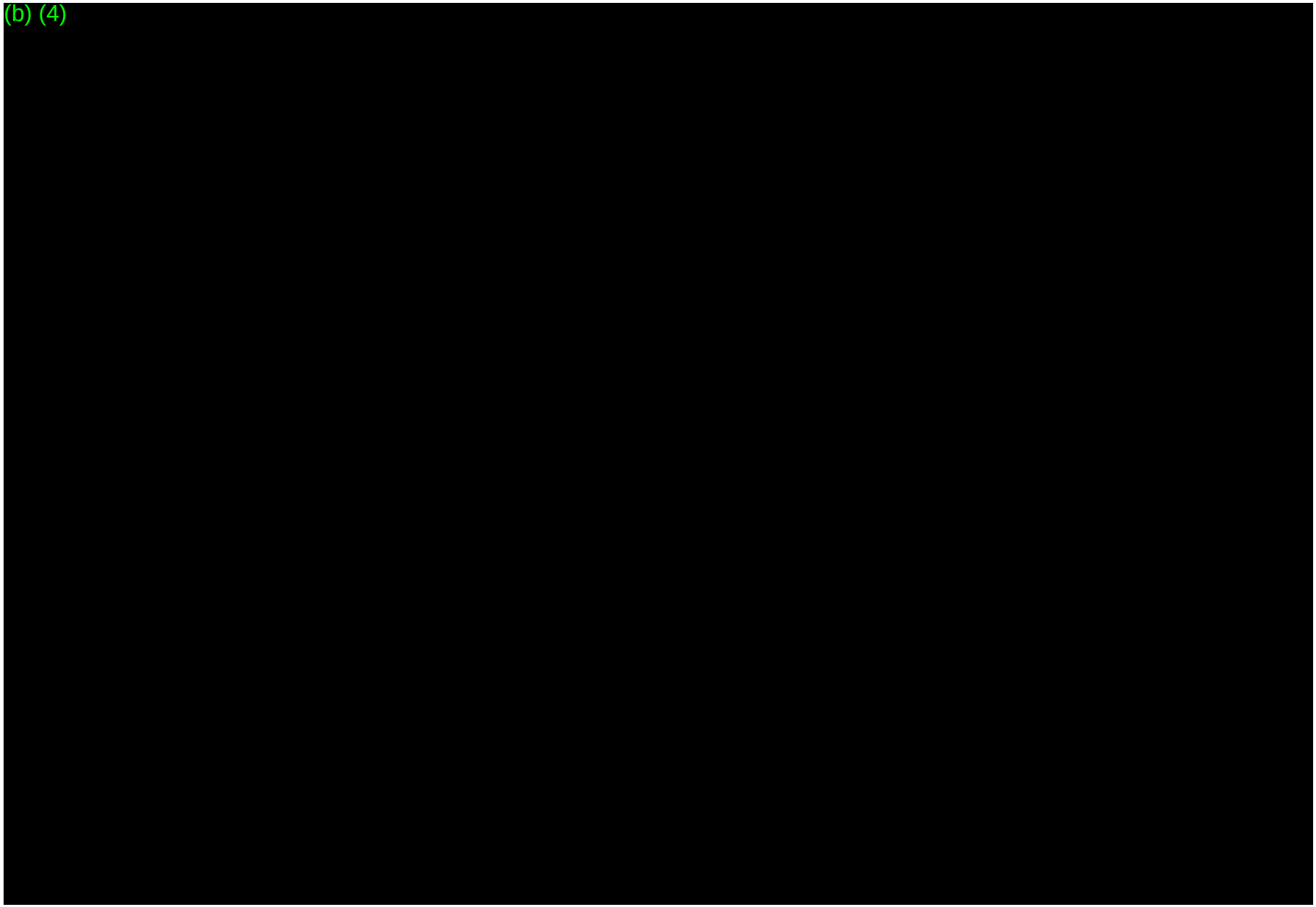

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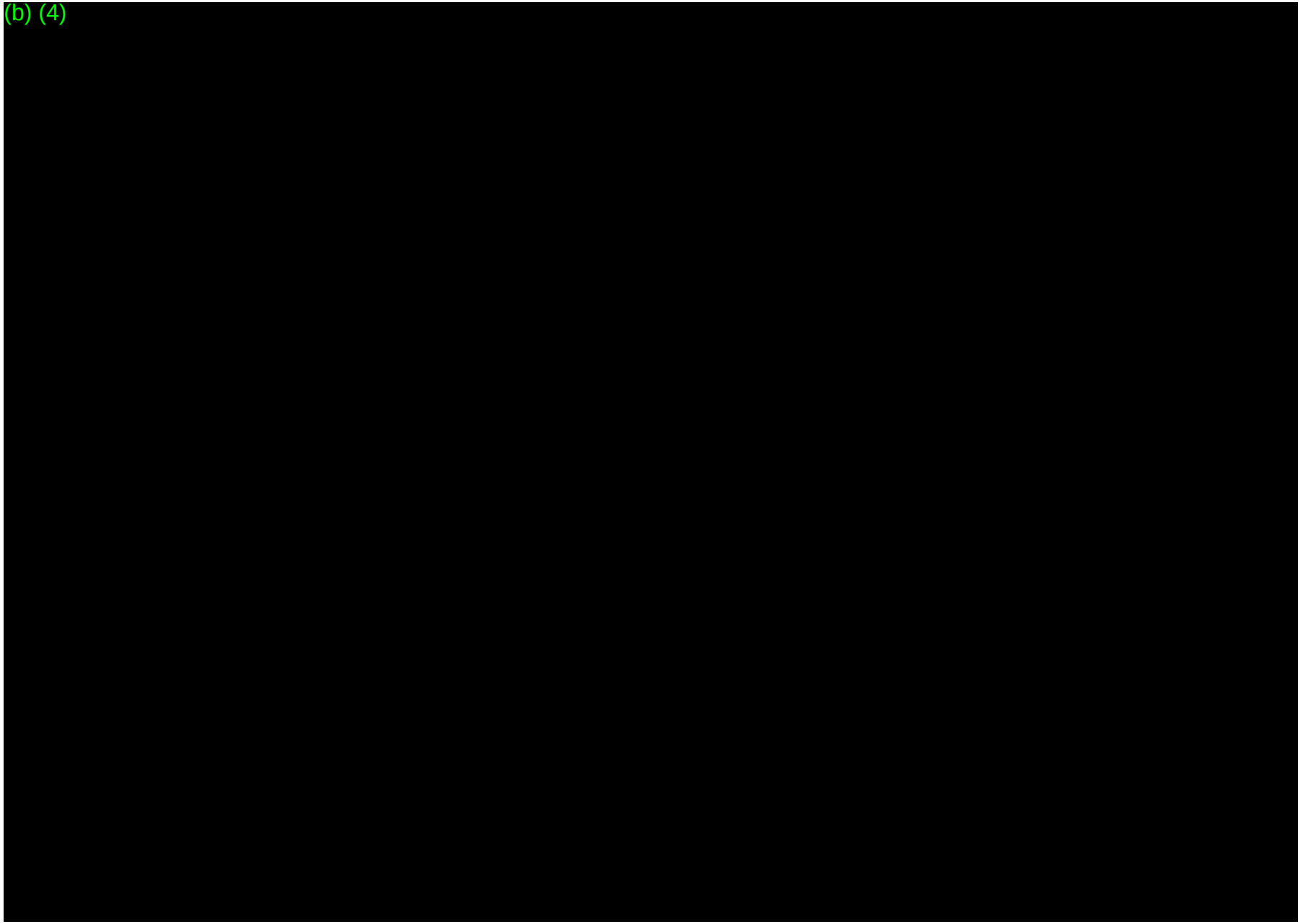

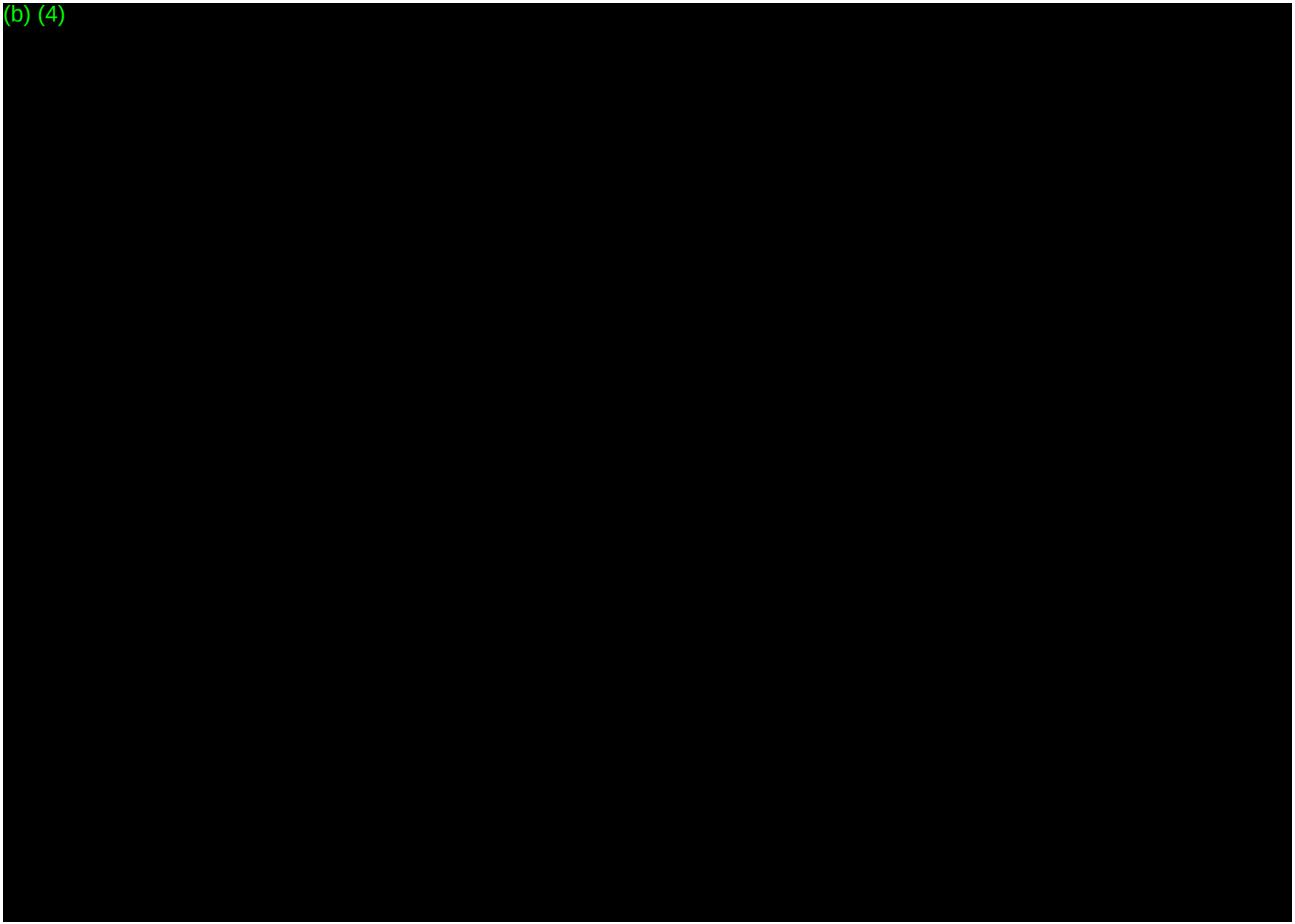

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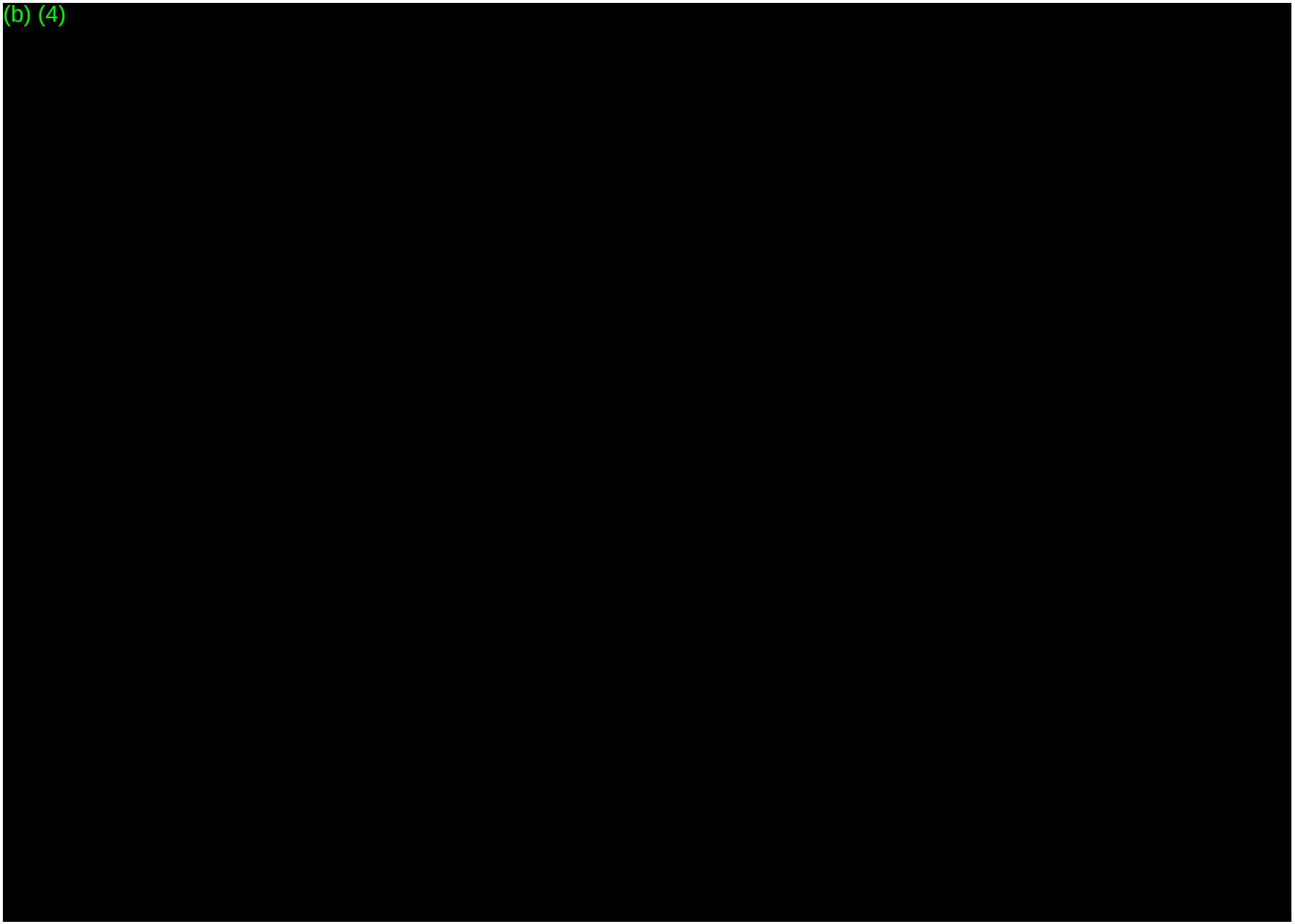

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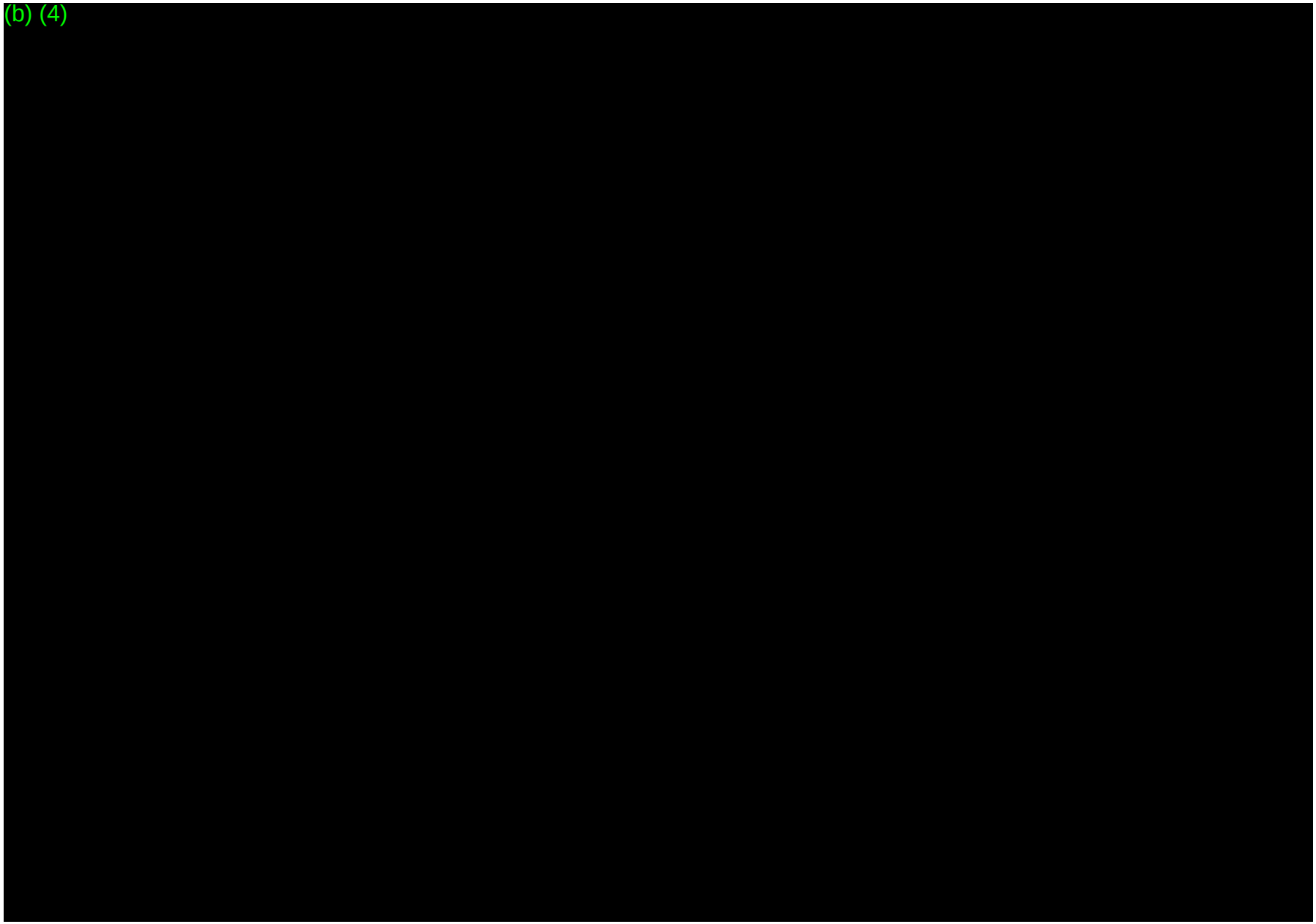

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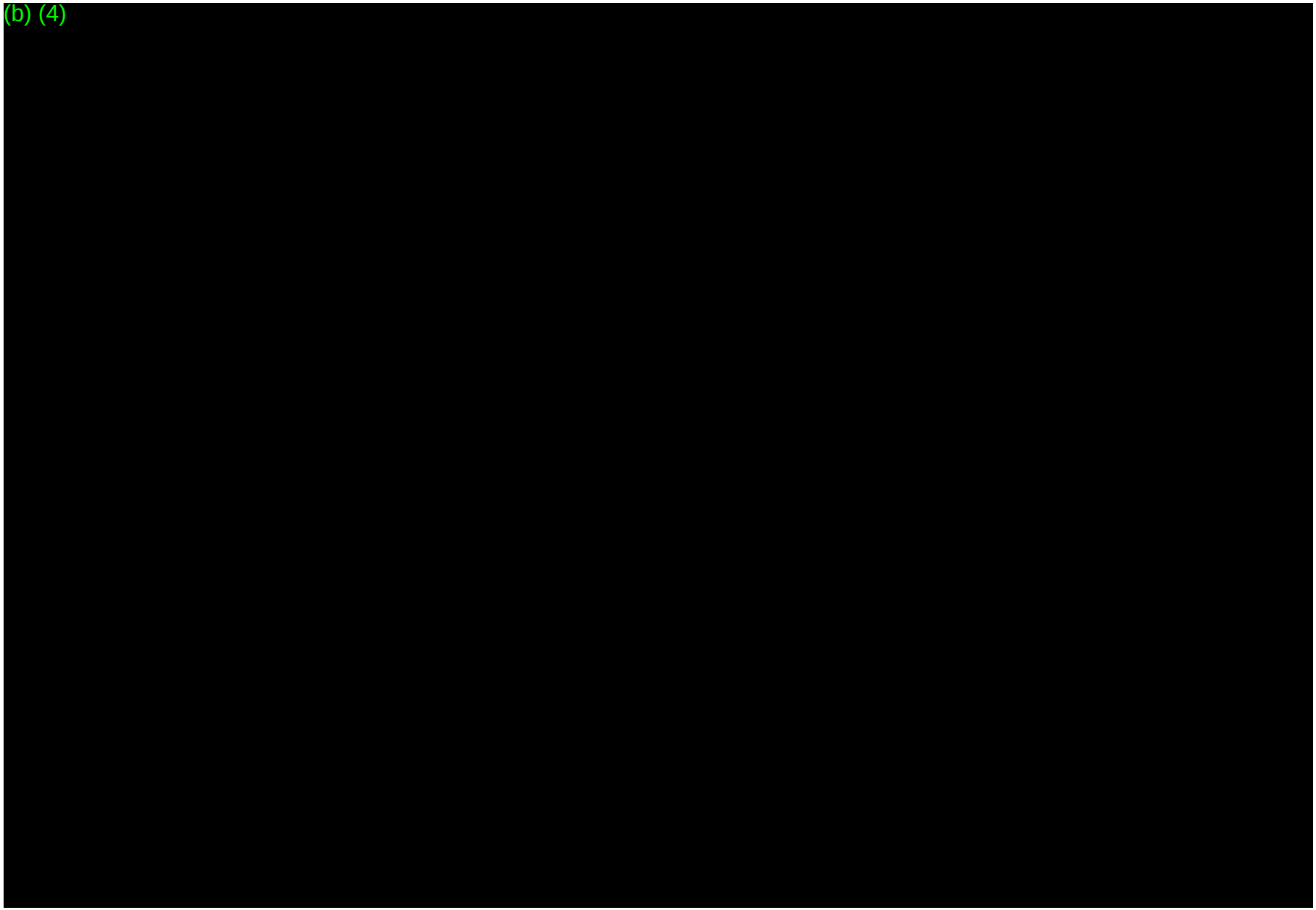

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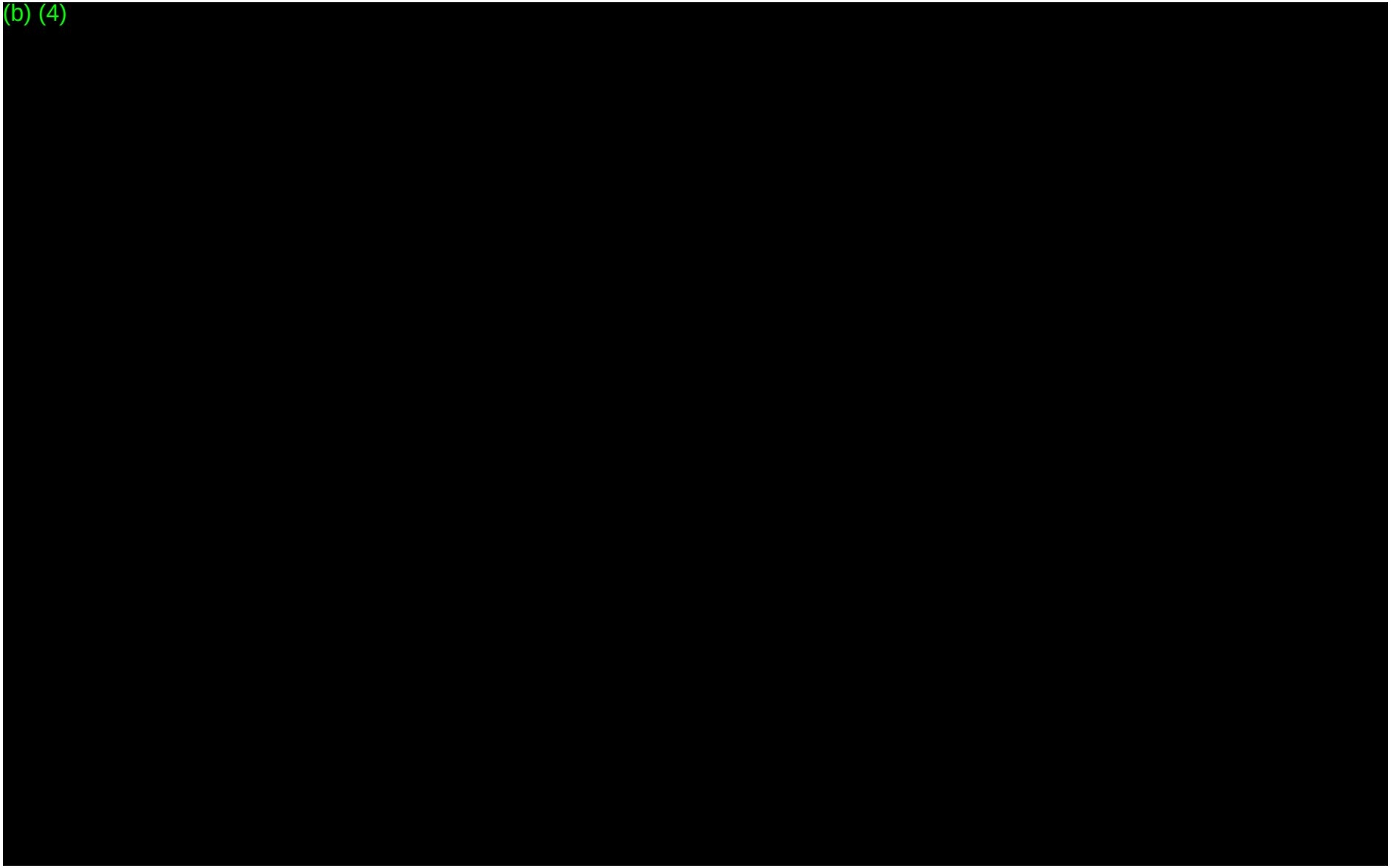

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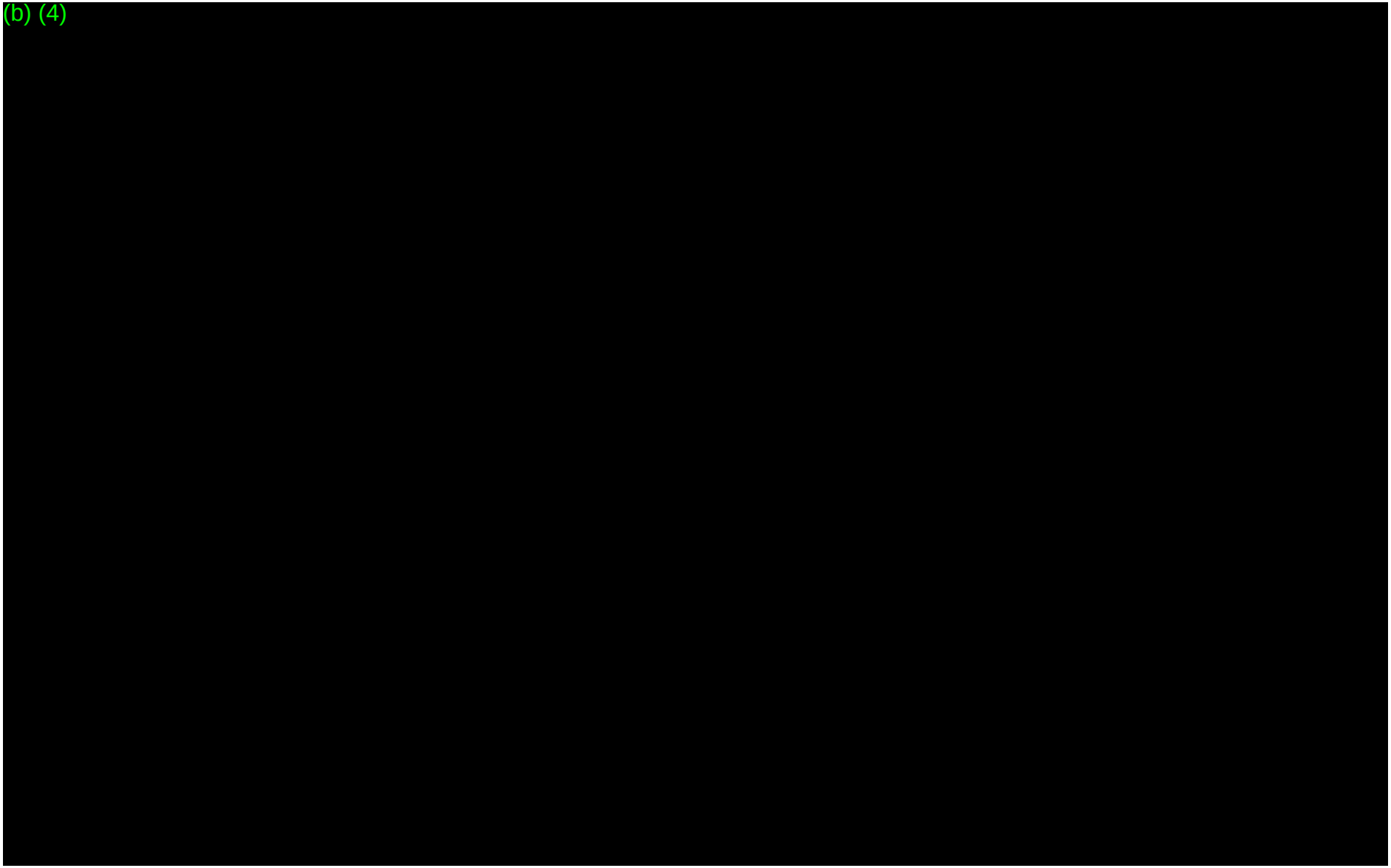

Appendix Q: Traceability Matrix (updated)

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Summary of Testing of Clinical Validation Units and Representative Units

July 14, 2018

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Algorithm Performance on AHA and MIT-BIH Databases

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Date: August 5, 2018

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Hello Luke,

I'm sending you my final memo for this file, I included the final IFU (per email of yesterday). Let me know if you have any additional question or concern. Let me know if you need the .doc.

As you can see in my memo, there are many aspects that were not properly addressed by the sponsor. I believe that these aspects can be potentially solved with an additional information hold (AINN); however I was verbally asked to reach a final-decision recommendation, therefore my recommendation is decline (DEND).

I remain available to discuss any additional question or clarification with you and review team.

Best regards,
Loriano.

Loriano Galeotti, PhD
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Appendix A: Device Hazard Analysis (Redline)

Revision History

Version #	Updates
1	Sent to FDA in Module 2
2	Updates to be more precise for clarification (see redlines). included acceptability table. Added final risk occurrence / severity.

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Appendix A: Device Hazard Analysis (Redline)

Revision History

Version #	Updates
1	Sent to FDA in Module 2
2	(August 20) Updates to be more precise for clarification (see redlines). included acceptability table. Added final risk occurrence / severity.
3	(August 27) Updates per FDA feedback (blue text)

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Appendix A: Device Hazard Analysis (Redline)

Hazard List

	Definition
Delay in Treatment	The user does not pursue and receive health care
Unnecessary Medical Care	The user seeks and receives unnecessary medical care
Data Loss	The ECG data has been modified, lost, or unavailable from its original state
Self Treatment	The user self treats with medication without consulting a physician
Annoyance	The user is inconvenienced, or is forced to spend time and/or resources unnecessarily

Harms List

Harm	Definition	Severity Level
Life Threatening Condition	An emergent, life-threatening condition, eg., heart attack, lethal arrhythmias (Ventricular tachycardia), or stroke	4
Increased Disease or Illness Risk	Increased risk of developing disease, Illness or injury, or risks associated with existing disease state	3
Anxiety	A feeling of worry, nervousness, or unease, typically about an imminent event or something with an uncertain outcome.	2
No Harm	There is no harm associated with this hazard.	1

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(b) (4) Mobile Medical App

De Novo Classification Request

August 13, 2018

Submitter	(b) (4)
Primary Submission Correspondent	Donna-Bea Tillman, Ph.D. Senior Consultant Biologics Consulting 1555 King St, Suite 300 Alexandria, VA 22314 410-531-6542 dtillman@biologicsconsulting.com
Secondary Submission Correspondent	Calley Herzog Senior Consultant Biologics Consulting 1555 King St, Suite 300 Alexandria, VA 22314 720-883-3633 cherzog@biologicsconsulting.com

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1. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

See Appendix A for the completed cover sheet, FDA Form 3514.

2. COVER LETTER

The final, signed cover letter is provided as a separate PDF document on the eCopy of this submission.

3. INDICATIONS FOR USE

(b)(4) Draft

[redacted]

4. ADMINISTRATIVE INFORMATION

This *De Novo* submission is prepared in accordance with FDA Guidance Document "*De Novo* Classification Process (Evaluation of Automatic Class III Designation)" issued on October 30, 2017.

4.1. Device Name

Device Common Name: Mobile ECG Analysis Software

Device Trade / Proprietary Name: (b) (4) Mobile Medical App

4.2. Submitter and Contact Information

Submitter Name: (b) (4)

Primary Submission Correspondent:

Donna-Bea Tillman, Ph.D.
Senior Consultant
Biologics Consulting
1555 King St, Suite 300
Alexandria, VA 22314
410-531-6542
dtillman@biologicsconsulting.com

Secondary Submission Correspondent:

Calley Herzog
Senior Consultant
Biologics Consulting
1555 King St, Suite 300
Alexandria, VA 22314
720-883-3633
cherzog@biologicsconsulting.com

4.3. Statements, Certifications, and Declarations of Conformity

N/A

5. REGULATORY HISTORY

5.1. Prior Submissions

(b) (4)

[redacted]

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14. PROPOSED LABELING

The (b) App experience can be found in Appendix D. Instructions for Use is provided in Appendix O.

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16. REFERENCES

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Luke Ralston
Scientific Reviewer
CDRH/ODE/DCD/CDDB

From: (b) (4)
Sent: Friday, September 07, 2018 1:16 AM
To: Ralston, Luke <Luke.Ralston@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Paulsen, Jessica <Jessica.Paulsen@fda.hhs.gov>; Drummond, Arielle <Arielle.Drummond@fda.hhs.gov>
Cc: Donna-Bea Tillman <donnabea@apple.com>; (b) (4) Donna-Bea Tillman <dtillman@biologicsconsulting.com>
Subject: Re: DEN180044

Team,
I inadvertently sent the Pages documents. Attached please find the PDFs.

Best,
(b) (4)

(b) (4)

On Sep 6, 2018, at 10:14 PM, (b) (4) wrote:

FDA team,

Attached please find revised IFU for (b) app, DEN180044, redline and clean versions.

Best,
(b) (4)

(b) (4)

<(b) App IFU Sep 6 Clean.pages>
<(b) App IFU Sep 6 Redline.pages>

Luke Ralston
Scientific Reviewer
CDRH/ODE/DCD/CDDB

From: (b) (4)
Sent: Friday, September 07, 2018 1:14 AM
To: Ralston, Luke <Luke.Ralston@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Paulsen, Jessica <Jessica.Paulsen@fda.hhs.gov>; Drummond, Arielle <Arielle.Drummond@fda.hhs.gov>
Cc: Donna-Bea Tillman <donnabea@apple.com>; (b) (4) Donna-Bea Tillman <dtillman@biologicsconsulting.com>
Subject: DEN180044

FDA team,

Attached please find revised IFU for (b) app, DEN180044, redline and clean versions.

Best,
(b) (4)

(b) (4)

Luke Ralston
Scientific Reviewer
CDRH/ODE/DCD/CDDB

From: (b) (4)
Sent: Monday, September 03, 2018 10:39 PM
To: Ralston, Luke <Luke.Ralston@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Paulsen, Jessica <Jessica.Paulsen@fda.hhs.gov>; Drummond, Arielle <Arielle.Drummond@fda.hhs.gov>
Cc: Donna-Bea Tillman <donnabea@apple.com>; Donna-Bea Tillman <dtillman@biologicsconsulting.com>; (b) (4)
Subject: DEN180044

Apple Confidential

FDA Team,

Attached please find responses to (b) questions from the call on Friday, August 31. The only outstanding questions pertains to the (b) (4). We will have that answer to you by EOD Wednesday, Sept. 4.

Best,
(b) (4)

(b) (4)

Luke Ralston
Scientific Reviewer
CDRH/ODE/DCD/CDDB
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1413&S=E

From: Ricci, Linda J
Sent: Friday, August 24, 2018 2:27 PM
To: Ralston, Luke <Luke.Ralston@fda.hhs.gov>
Cc: Paulsen, Jessica <Jessica.Paulsen@fda.hhs.gov>
Subject: RE: DEN180044 Remaining deficiencies for interactive review

Sent them today. Please note that they were edited. Happy to chat about edits if need be.

Attached redline version of deficiencies that were sent.

Linda Ricci
Associate Director ODE DH
Center for Devices and Radiologic Health
Office of Device Evaluation
U.S. Food and Drug Administration
Tel: 301-796-6325
Linda.Ricci@fda.hhs.gov<mailto:Linda.Ricci@fda.hhs.gov>
(OPEQ Pilot: Immediate Office/Regulations, Policy, and Guidance Staff)

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=400&D=440&B=442&E=&S=E

From: Ralston, Luke
Sent: Friday, August 24, 2018 1:07 PM
To: Ricci, Linda J
<Linda.Ricci@fda.hhs.gov<mailto:Linda.Ricci@fda.hhs.gov>>
Subject: RE: DEN180044 Remaining deficiencies for interactive review

Did you send these yesterday or today? I'm trying to update my interactive review timeline.

Luke Ralston
Scientific Reviewer
CDRH/ODE/DCD/CDDB
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1413&S=E

From: Ricci, Linda J

Sent: Thursday, August 23, 2018 3:14 PM
To: Ralston, Luke
<Luke.Ralston@fda.hhs.gov<mailto:Luke.Ralston@fda.hhs.gov>>
Subject: Re: DEN180044 Remaining deficiencies for interactive review

Will do

_____

From: Ralston, Luke
<Luke.Ralston@fda.hhs.gov<mailto:Luke.Ralston@fda.hhs.gov>>
Date: August 23, 2018 at 2:50:38 PM EDT
To: Ricci, Linda J
<Linda.Ricci@fda.hhs.gov<mailto:Linda.Ricci@fda.hhs.gov>>
Cc: Paulsen, Jessica
<Jessica.Paulsen@fda.hhs.gov<mailto:Jessica.Paulsen@fda.hhs.gov>>
Subject: DEN180044 Remaining deficiencies for interactive review

Linda,

Please forward these remaining deficiencies to the sponsor:

(b) (4)

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(b) (4)

(b) (4)

Tel: (301) 796-6362
Luke.Ralston@fda.hhs.gov<mailto:Luke.Ralston@fda.hhs.gov>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1413&S=E

Luke Ralston
Scientific Reviewer
CDRH/ODE/DCD/CDDB

From: Donna-Bea Tillman <dtillman@biologicsconsulting.com>
Sent: Thursday, August 23, 2018 9:42 PM
To: Ralston, Luke <Luke.Ralston@fda.hhs.gov>; Fang, Kan <Kan.Fang@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Drummond, Arielle <Arielle.Drummond@fda.hhs.gov>; Paulsen, Jessica <Jessica.Paulsen@fda.h v>
Subject: Follow-up on (b) (4) ECGs excluded from waveform analysis

FDA (b) (4) Team:

(b) (4)

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Luke Ralston
Scientific Reviewer
CDRH/ODE/DCD/CDDB
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1413&S=E

From: Donna-Bea Tillman <dtillman@biologicsconsulting.com>
Sent: Tuesday, August 28, 2018 9:43 PM
To: Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Paulsen, Jessica <Jessica.Paulsen@fda.hhs.gov>; Ralston, Luke <Luke.Ralston@fda.hhs.gov>; Drummond, lle <Arielle.Drummond@fda.hhs.gov>
Subject: (b) additional information

FDA Review Team:

Attached please find our responses to your (b) Additional Information request of August 24.

Plea te that it is taking us a little longer than expected to compile the (b) "platform validation" testing results. We will provide that info on to you tomorrow afternoon eastern time.

Donna-Bea

Donna-Bea Tillman, Ph.D, FRAPS
Team Leader and Senior Consultant, Medical Devices

Biologics Consulting
PHARMACEUTICALS DEVICES BIOLOGICS
(410) 531-6542 - Direct
(703) 739.5695 - Main Office
dtillman@biologicsconsulting.com<mailto:dtillman@biologicsconsulting.com>
BiologicsConsulting.com

Luke Ralston
Scientific Reviewer
CDRH/ODE/DCD/CDDB
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1413&S=E

From: (b) (4)
Sent: Monday, August 27, 2018 11:49 PM
To: Ralston, Luke <Luke.Ralston@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Paulsen, Jessica <Jessica.Paulsen@fda.hhs.gov>; Drummond, Arielle <Arielle.Drummond@fda.hhs.gov>
Cc: (b) (4) Donna-Bea Tillman <donnabea@apple.com>; (b) (4)
Subject: (b) App DEN180044

Apple Confidential

FDA team,
Attached please find responses to questions emailed on August 23.

Best,
(b) (4)

(b) (4)

Luke Ralston
Scientific Reviewer
CDRH/ODE/DCD/CDDB
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1413&S=E

From: (b) (4)
Sent: Monday, August 20, 2018 11:59 PM
To: Ralston, Luke <Luke.Ralston@fda.hhs.gov>
Cc: Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Paulsen, Jessica <Jessica.Paulsen@fda.hhs.gov>; Drummond, Arielle <Arielle.Drummond@fda.hhs.gov>; Donna-Bea Tillman <donnabea@apple.com>; Calley Herzog <calley_herzog@apple.com>; (b) (4)
Subject: (b) Documents-DEN180044

Luke,

Attached please find a document with questions and answers regarding DEN180044 and associated attachments. Please let us know if you have any additional questions.

Best,
(b) (4)

(b) (4)

Luke Ralston
Scientific Reviewer
CDRH/ODE/DCD/CDDB
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1413&S=E

From: Donna-Bea Tillman <dtillman@biologicsconsulting.com>
Sent: Tuesday, September 04, 2018 9:01 PM
To: Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Paulsen, Jessica <Jessica.Paulsen@fda.hhs.gov>; Drummond, Arielle <Arielle. ond@fda.hhs.gov>; Ralston, Luke <Luke.Ralston@fda.hhs.gov>
Subject: (b) (4) HR Spec response

FDA Team:

  ed please find our response regarding the Heart Rate spec for (b) (4) Please let me know if you have any additional questions.

Donna-Bea

Donna-Bea Tillman, Ph.D, FRAPS
Team Leader and Senior Consultant, Medical Devices

Biologics Consulting
PHARMACEUTICALS DEVICES BIOLOGICS
(410) 531-6542 - Direct
(703) 739.5695 - Main Office
dtillman@biologicsconsulting.com<mailto:dtillman@biologicsconsulting.com>
BiologicsConsulting.com

Luke Ralston
Scientific Reviewer
CDRH/ODE/DCD/CDDB
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1413&S=E

From: Donna-Bea Tillman <dtillman@biologicsconsulting.com>
Sent: Wednesday, August 29, 2018 7:45 PM
To: Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Ralston, Luke <Luke.Ralston@fda.hhs.gov>; Paulsen, Jessica <Jessica.Paulsen@fda.hhs.gov>; Drummond, Arielle <Arielle.[redacted]ond@fda.hhs.gov>
Subject: (b)(4) Platform Inputs

FDA Team:

The attached document provides the test results for the (b)(4) platform inputs.
Please let me know if you have any questions.

Donna-Bea

Donna-Bea Tillman, Ph.D, FRAPS
Team Leader and Senior Consultant, Medical Devices

Biologics Consulting
PHARMACEUTICALS DEVICES BIOLOGICS
(410) 531-6542 - Direct
(703) 739.5695 - Main Office
dtillman@biologicsconsulting.com<mailto:dtillman@biologicsconsulting.com>
BiologicsConsulting.com

Luke Ralston
Scientific Reviewer
CDRH/ODE/DCD/CDDB
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1413&S=E

From: Ricci, Linda J
Sent: Thursday, August 23, 2018 11:09 AM
To: Donna-Bea Tillman (dtillman@biologicsconsulting.com) <dtillman@biologicsconsulting.com>
Cc: Ralston, Luke <Luke.Ralston@fda.hhs.gov>; Paulsen, Jessica <Jessica.Paulsen@fda.hhs.gov>; Drummond, Arielle <Arielle.Drummond@fda.hhs.gov>; Yarkony, Nathalie <Nathalie.Yarkony@fd .gov>
Subject: SW def for (b) (4)

Good morning,

Please find attached software def for (b) (4) [redacted] t these on them and we can have discuss, if needed, sooner rather than later.

Thanks
--Linda

Linda Ricci
Associate Director ODE DH
Center for Devices and Radiologic Health
Office of Device Evaluation
U.S. Food and Drug Administration
Tel: 301-796-6325
Linda.Ricci@fda.hhs.gov<mailto:Linda.Ricci@fda.hhs.gov>
(OPEQ Pilot: Immediate Office/Regulations, Policy, and Guidance Staff)<http://www.fda.gov/>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
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Attachment 1 (b) (4) Testing Report

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(b)(5) Internal FDA Deliberations

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(b)(5) Internal FDA Deliberations

DEN180044 – (b) (4) (Apple) – (b) (4)

Date: Tuesday, January 28, 2020

Consultant: Loriano Galeotti, PhD
(FDA / CDRH / Office of Device Evaluation / Division of Cardiovascular Devices / Cardiac Diagnostic Devices)

Lead reviewer: Luke Ralston.

Instructions/comments from Lead Reviewer: TBD.

Scope: This memo covers engineering related to of ECG acquisition and processing and AF detection algorithm. Other aspects are not reviewed unless otherwise noted.

Note: this memo and deficiencies are intended for internal discussion only, and should not be communicated to the sponsor unless otherwise indicated. Minor edits can be made to the deficiencies, in case of doubt or major edits, please contact the consultant.
Color coding (unless otherwise specified): plain font my comment; *italics* quotes from the sponsor;
highlight: red = inadequate, green = adequate, yellow=comment to the lead reviewer;
When referencing "this" submission, I'm meaning the current submission under review as indicated in the header of the present document, unless otherwise specified.

Outstanding deficiencies are denoted by highlighted red font while deficiencies that were previously communicated to the sponsor are in red.

Summary/device description

Indications for use

(b)(4) Draft

(b) (4)

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Summary

The sponsor provided multiple clinical and non-clinical data to demonstrate the performance of the device.

The information provided is inadequate to determine the safety and effectiveness of the device. I identified multiple aspects that need to be addressed to determine the safety and effectiveness of the device, listed in format of deficiencies below. During the review of this file there were multiple rounds of interactive deficiencies and responses that addressed some of my questions but not all them. The amount of interaction also made extremely difficulty to keep track of the changes in documentation and responses.

I recommend disapproval for this file since the sponsor did not provide adequate rationale and data to allow the agency to determine the safety and effectiveness of the device.

Brief analysis of the performance data provided

The sponsor provided testing per ANSI AAMI EC57 (app V). This standard is recognized by FDA and is commonly used for assessing performance in arrhythmia detectors in pre-market notifications (510(k)).

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Level of Evidence Questions for Benefit-Risk Assessment

Form

Applies To: ODE and OIR

Date Effective: 06/20/2018

Use FEEDBACK✓CDRH to provide comments on this document (include Doc # 01126)

Purpose: This form is intended to serve as a complementary form to the Benefit-Risk Decision Support Tool to guide review staff regarding critical elements that should be considered as part of the thought-process associated with benefit-risk assessments. This form is intended for inclusion as part of the administrative record and also intended to facilitate management's review during the oversight process in order to ascertain which elements were considered by review staff.

Instructions: Consider questions 1-8 for Column A (the proposed Indication for Use), until you reach a recommendation to either approve/grant or move to Column B. When considering an acceptable, modified Indications for Use, interact with the sponsor to reach agreement on a modified Indication for Use.

Beta Testing Instructions: Send feedback concerning any issue identified as a result of using the revised B-R tools to Benefit-RiskTools@fda.hhs.gov. Upon completion of this form and the Decision Support Tool (when the documents are used as part of a management interim meeting or for supporting a final decision), email the completed documents to Benefit-RiskTools@fda.hhs.gov. Please note that Benefit-RiskTools@fda.hhs.gov is an internal email address for the purpose of the beta testing. Do not disseminate outside of CDRH.

Premarket Submission Type	☐ PMA ☒ De Novo
PMA/De Novo Number:	DEN180044
Device Name:	(b) (4)
Applicant:	(b) (4)
Medical Officer:	Kan Fang, MD
Scientific Reviewer:	Luke Ralston
Worksheet Completion Date:	August 31, 2018
Review Stage:	☐ Interim (Complete Q1-4, select considerations, and explain in text boxes. There is no need to answer Yes/No for Q5-8.) ☒ Final (Complete Q1-5 and Q6-8, as needed.)
Device Description:	

(b)(4) Draft

[redacted]

Assessment of Benefit

1. **Is there any evidence of clinical benefit?**

   Is a clinical benefit demonstrated for the device for this indication (e.g., from any one or more of the primary and/or secondary datasets or from associated real-world evidence)? Benefit may be considered in terms of how a patient feels, functions, survives, or an acceptable surrogate outcome. Benefit may also be considered in terms of convenience in managing or diagnosing a disease or condition. Benefit should be considered based on the clinical assessment of the data, whether or not the results are statistically significant. *Select any of the following that demonstrate benefit.*

A	B	
		A favorable change in at least 1 clinical assessment that:
☐	☐	Is equal to or greater than seen in the control group
☒	☐	Meets a predetermined performance goal
☐	☐	Meets or surpasses a minimally important clinical difference
☒	☐	Is equal to or greater than seen with other available modalities for the condition
☐	☐	Would be meaningful to patients considering the severity, chronicity, etc., of the condition, taking into consideration patient-reported outcomes and health-related quality of life

☐ ☐ A favorable change in non-clinical data or modeling that is deemed to be predictive of clinical outcomes

☒ ☐ A favorable clinical performance characteristic (e.g., sensitivity/PPA,[1] specificity/NPA[2], etc.) for the screening, diagnosis, prognosis, monitoring or treatment selection

☐ ☐ Acceptable performance characteristics for analytical validation of the device

☐ ☐ Other(s) Click here to list other(s)

☐ ☐ None

Q1: Is there any evidence of clinical benefit?

A B

☒ ☐ YES → Continue to Question 2

☐ ☐ NO → Move one column to the right (or, if final column has been reached and you have determined there is no evidence of clinical benefit, do not approve the application/request)

[1] PPA: Positive Percent Agreement

[2] NPA: Negative Percent Agreement

2. What is the degree of uncertainty for the benefits?

Recognizing that some degree of uncertainty always exists, select the sources of uncertainty, if applicable, in the data that affect your assessment of the clinical benefit. Consider sensitivity, specificity, accuracy, precision, reproducibility, etc. (analytical and/or clinical validation, as applicable).

A	B	
☐	☐	Inconsistent or conflicting results between studies
☐	☐	Wide confidence intervals surrounding the point estimate(s) and/or odds ratio(s))
☐	☐	A significantly underpowered study with statistical insignificance in outcome measure(s)
☐	☐	High subject or specimen loss-to-follow-up at critical assessment point(s)
☐	☐	Large amount of missing data at critical assessment time(s) +/- imputation
☐	☐	Significant number of major protocol deviations
☐	☐	Impact of confounding interventions or physiological factors
☐	☐	Inconsistent user experience or user experience not representative of likely real world user
☒	☐	Unclear correlation between pre-selected enriched data and clinical performance
☐	☐	Surrogate endpoint has not yet been demonstrated to correlate with a clinical outcome
☐	☐	Real World Evidence (RWE) is not relevant or reliable for the purposes of the proposed analysis
☐	☐	Inspectional findings
☒	☐	Study design or results lead to lack of generalizability for the intended use population or specific clinical subpopulations.
☐	☐	Physiological or clinically meaningful range of the diagnostic output is unknown or generalizability of proposed clinical cut-off is unknown
☐	☐	Imperfect comparator method used to calculate performance characteristics
☐	☐	Other(s) Click here to list other(s)
☐	☐	None

Q2: What is the degree of uncertainty for the benefits?

A	B	
☐	☐	Low → Continue to Question 3
☒	☐	Med → Continue to Question 3
☐	☐	High → Continue to Question 3

Summary of the Assessment of Benefit

For the Proposed Indications for Use (Column A):

(b)(4) Draft

(b) (4)

(b) (4)

Assessment of Risk

3. Are known/probable risks more than minimal?

Select the elements that apply for known/probable risks that are more than minimal.

A	B	
☐	☐	Adverse events (AEs) or outcomes related to the device itself
☐	☐	AEs or outcomes related to the use of the device or procedure to use the device
☐	☐	AEs or outcomes related to anesthesia or sedation to use the device
☐	☐	AEs or outcomes due to subsequent tests/treatments needed (e.g., radiation from CT scans)
☐	☐	AEs or outcomes, not seen in the study/data, but probable based on "class effect" or events known to occur with similar technologies
☒	☐	False positive/false negative/failed to provide a result for diagnostics
☐	☐	Treatment or diagnostic intended to be used as a standalone rather than an adjunctive use
☐	☐	Other(s) [Click here to list other(s)]
☐	☐	None

Q3: Are known/probable risks more than minimal?

A	B	
☐	☐	YES → Continue to Question 4
☒	☐	NO → Continue to Question 4

4. What is the degree of uncertainty for the risks?

Recognizing that some degree of uncertainty always exists, select the sources uncertainty, if applicable, in the data regarding the adverse events/outcomes or risks.

A	B	
☐	☐	Insufficient patient numbers to detect serious events or false positives/false negatives
☐	☐	Insufficient duration of follow-up to detect delayed/late events
☒	☐	Lack of data on repeated exposure to the device/use
☐	☐	Inconsistent or conflicting results between studies
☐	☐	Proper evaluations not performed as part of the study protocol to adequately detect certain AEs
☐	☐	Poor or inconsistent adverse event definitions and documentation
☐	☐	Events likely confounded by, and attributed to, other comorbidities or treatment modalities
☐	☐	High subject loss-to-follow-up at critical assessment point(s)
☐	☐	Large amount of missing data at critical assessment time(s) +/- imputation
☐	☐	Significant number of major protocol deviations
☐	☐	Inconsistent user experience or user experience not representative of likely real world user
☒	☐	Concerns related to performance characteristics (e.g., sensitivity/PPA, specificity/NPA)
☐	☐	Imperfect comparator method used to calculate performance characteristics
☐	☐	Other(s) Click here to list other(s)
☐	☐	None

Q4: What is the degree of uncertainty for the risks?

A	B	
☒	☐	Low → Continue to Question 5
☐	☐	Med → Continue to Question 5
☐	☐	High → Continue to Question 5

Summary of the Assessment of Risk

For the Proposed Indications for Use (Column A):

To record, store, transfer, and display Lead I ECG signals

Type of Risk

The device does not cause direct physical harms.

(b) (4)

[redacted]

(b) (4)

(b) (4)

Level of Evidence Questions for Benefit-Risk Assessment

Form

Applies To: ODE and OIR

Date Effective: 06/20/2018

Use FEEDBACK✓CDRH to provide comments on this document (include Doc # 01126)

Purpose: This form is intended to serve as a complementary form to the Benefit-Risk Decision Support Tool to guide review staff regarding critical elements that should be considered as part of the thought-process associated with benefit-risk assessments. This form is intended for inclusion as part of the administrative record and also intended to facilitate management's review during the oversight process in order to ascertain which elements were considered by review staff.

Instructions: Consider questions 1-8 for Column A (the proposed Indication for Use), until you reach a recommendation to either approve/grant or move to Column B. When considering an acceptable, modified Indications for Use, interact with the sponsor to reach agreement on a modified Indication for Use.

Beta Testing Instructions: Send feedback concerning any issue identified as a result of using the revised B-R tools to Benefit-RiskTools@fda.hhs.gov. Upon completion of this form and the Decision Support Tool (when the documents are used as part of a management interim meeting or for supporting a final decision), email the completed documents to Benefit-RiskTools@fda.hhs.gov. Please note that Benefit-RiskTools@fda.hhs.gov is an internal email address for the purpose of the beta testing. Do not disseminate outside of CDRH.

Premarket Submission Type	☐ PMA ☒ De Novo
PMA/De Novo Number:	DEN180044
Device Name:	(b) (4)
Applicant:	(b) (4)
Medical Officer:	Kan Fang, MD
Scientific Reviewer:	Luke Ralston
Worksheet Completion Date:	August 17, 2018
Review Stage:	☒ Interim (Complete Q1-4, select considerations, and explain in text boxes. There is no need to answer Yes/No for Q5-8.) ☐ Final (Complete Q1-5 and Q6-8, as needed.)
Device Description:	

(b)(4) Draft

(b)(4) Draft

[redacted]

Modified Indication for Use (if different than proposed) – Column B:

N/A

Assessment of Benefit

1. **Is there any evidence of clinical benefit?**

   Is a clinical benefit demonstrated for the device for this indication (e.g., from any one or more of the primary and/or secondary datasets or from associated real-world evidence)? Benefit may be considered in terms of how a patient feels, functions, survives, or an acceptable surrogate outcome. Benefit may also be considered in terms of convenience in managing or diagnosing a disease or condition. Benefit should be considered based on the clinical assessment of the data, whether or not the results are statistically significant. *Select any of the following that demonstrate benefit.*

A	B	A favorable change in at least 1 clinical assessment that:
☐	☐	Is equal to or greater than seen in the control group
☒	☐	Meets a predetermined performance goal
☐	☐	Meets or surpasses a minimally important clinical difference
☒	☐	Is equal to or greater than seen with other available modalities for the condition
☐	☐	Would be meaningful to patients considering the severity, chronicity, etc., of the condition, taking into consideration patient-reported outcomes and health-related quality of life

☐ ☐ A favorable change in non-clinical data or modeling that is deemed to be predictive of clinical outcomes

☒ ☐ A favorable clinical performance characteristic (e.g., sensitivity/PPA,[1] specificity/NPA[2], etc.) for the screening, diagnosis, prognosis, monitoring or treatment selection

☐ ☐ Acceptable performance characteristics for analytical validation of the device

☐ ☐ Other(s) Click here to list other(s)

☐ ☐ None

Q1: Is there any evidence of clinical benefit?

A B

☒ ☐ YES → Continue to Question 2

☐ ☐ NO → Move one column to the right (or, if final column has been reached and you have determined there is no evidence of clinical benefit, do not approve the application/request)

[1] PPA: Positive Percent Agreement

[2] NPA: Negative Percent Agreement

2. What is the degree of uncertainty for the benefits?

Recognizing that some degree of uncertainty always exists, select the sources of uncertainty, if applicable, in the data that affect your assessment of the clinical benefit. Consider sensitivity, specificity, accuracy, precision, reproducibility, etc. (analytical and/or clinical validation, as applicable).

A	B	
☐	☐	Inconsistent or conflicting results between studies
☐	☐	Wide confidence intervals surrounding the point estimate(s) and/or odds ratio(s))
☐	☐	A significantly underpowered study with statistical insignificance in outcome measure(s)
☐	☐	High subject or specimen loss-to-follow-up at critical assessment point(s)
☐	☐	Large amount of missing data at critical assessment time(s) +/- imputation
☐	☐	Significant number of major protocol deviations
☐	☐	Impact of confounding interventions or physiological factors
☐	☐	Inconsistent user experience or user experience not representative of likely real world user
☒	☐	Unclear correlation between non-clinical data, pre-selected enriched data, or computer modeling and clinical performance
☐	☐	Surrogate endpoint has not yet been demonstrated to correlate with a clinical outcome
☐	☐	Real World Evidence (RWE) is not relevant or reliable for the purposes of the proposed analysis
☐	☐	Inspectional findings
☐	☐	Study design or results lead to lack of generalizability for the intended use population or specific clinical subpopulations.
☐	☐	Physiological or clinically meaningful range of the diagnostic output is unknown or generalizability of proposed clinical cut-off is unknown
☐	☐	Imperfect comparator method used to calculate performance characteristics
☐	☐	Other(s) Click here to list other(s)
☐	☐	None

Q2: What is the degree of uncertainty for the benefits?

A	B	
☒	☐	Low → Continue to Question 3
☐	☐	Med → Continue to Question 3
☐	☐	High → Continue to Question 3

Summary of the Assessment of Benefit

For the Proposed Indications for Use (Column A):

(b)(4) Draft

(b) (4)

(b) (4)

Assessment of Risk

3. Are known/probable risks more than minimal?

Select the elements that apply for known/probable risks that are more than minimal.

A	B	
☐	☐	Adverse events (AEs) or outcomes related to the device itself
☐	☐	AEs or outcomes related to the use of the device or procedure to use the device
☐	☐	AEs or outcomes related to anesthesia or sedation to use the device
☐	☐	AEs or outcomes due to subsequent tests/treatments needed (e.g., radiation from CT scans)
☐	☐	AEs or outcomes, not seen in the study/data, but probable based on "class effect" or events known to occur with similar technologies
☒	☐	False positive/false negative/failed to provide a result for diagnostics
☐	☐	Treatment or diagnostic intended to be used as a standalone rather than an adjunctive use
☐	☐	Other(s) [Click here to list other(s)]
☐	☐	None

Q3: Are known/probable risks more than minimal?

A	B	
☒	☐	YES → Continue to Question 4
☐	☐	NO → Continue to Question 4

4. What is the degree of uncertainty for the risks?

Recognizing that some degree of uncertainty always exists, select the sources uncertainty, if applicable, in the data regarding the adverse events/outcomes or risks.

A	B	
☐	☐	Insufficient patient numbers to detect serious events or false positives/false negatives
☐	☐	Insufficient duration of follow-up to detect delayed/late events
☒	☐	Lack of data on repeated exposure to the device/use
☐	☐	Inconsistent or conflicting results between studies
☐	☐	Proper evaluations not performed as part of the study protocol to adequately detect certain AEs
☐	☐	Poor or inconsistent adverse event definitions and documentation
☐	☐	Events likely confounded by, and attributed to, other comorbidities or treatment modalities
☐	☐	High subject loss-to-follow-up at critical assessment point(s)
☐	☐	Large amount of missing data at critical assessment time(s) +/- imputation
☐	☐	Significant number of major protocol deviations
☐	☐	Inconsistent user experience or user experience not representative of likely real world user
☒	☐	Concerns related to performance characteristics (e.g., sensitivity/PPA, specificity/NPA)
☐	☐	Imperfect comparator method used to calculate performance characteristics
☐	☐	Other(s) Click here to list other(s)
☐	☐	None

Q4: What is the degree of uncertainty for the risks?

A	B	
☐	☐	Low → Continue to Question 5
☒	☐	Med → Continue to Question 5
☐	☐	High → Continue to Question 5

Summary of the Assessment of Risk

For the Proposed Indications for Use (Column A):

To record, store, transfer, and display Lead I ECG signals

Type of Risk

The device does not cause direct physical harms.

(b) (4)

[redacted]

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b)(5) Draft

(b)(5) Draft

(b)(5) Draft

(b)(5) Draft

[redacted]

Human Factors (HF) Consult Memo

Consult Number:	CON1819925
Document Number:	DEN180044
Applicant:	(b) (4)
Trade Name:	(b) (4)
Consult Type:	Human Factors
Requestor:	Luke Ralston [LTR] luke.ralston@fda.hhs.gov ; 301-796-6362
Requestor Home:	CDRH\ OHT2\ DHT2A\ THT2A3
Requested Consultant:	
Gatekeeper / Consultant:	Kimberly Kontson [KIMBERLY.KONTSON] kimberly.kontson@fda.hhs.gov ; 301-796-4990
Consultant Home:	CDRH\ OSEL\ DBP
Date Requested:	August 15, 2018
Due Date:	August 20, 2018
Instructions:	

Indications for use: (b)(4) Draft [redacted]

Key considerations for conducting a HF review: Is the supporting documentation adequate to demonstrate that the subject device UI supports safe & effective use?

Date consult sent: August 17, 2018

(b)(4) Test Data [redacted]

(b)(4) Test Data

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U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

EMC/Electrical Safety Consult Memo

Date: 28 January 2020

To: Luke Ralston
CDRH/THT2A3

From: Aneesh Deoras
CDRH/THT2A2

Re: DEN180044 - CON1819926
(b) (4)
(b) (4)

Recommendation

Recommending one deficiency to address an inadequate EMC mitigation.

Introduction

This memo contains an assessment of the electrical safety and electromagnetic compatibility information provided in DEN180044. (b) (4) Those memos, including any new comments, will be consolidated here.

Subject Device Description

(b)(4) Draft

Indications for Use

(b)(4) Draft

(b)(4) Draft

[redacted]

Predicate and Reference Devices

De Novo application as FDA previously stated that there is no legally marketed predicate device.

Review

Note:

The structure of this memo includes my prior comments on (b) (4) *followed by a review of the new information provided in DEN180044.*

(b) (5)

[redacted]

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(b) (5), (b) (4)

(b) (5), (b) (4)

DEN180044 – (b) (4) (Apple) – (b) (4)

Date: Tuesday, January 28, 2020

Consultant: Loriano Galeotti, PhD
(FDA / CDRH / Office of Device Evaluation / Division of Cardiovascular Devices / Cardiac Diagnostic Devices)

Lead reviewer: Luke Ralston.

Instructions/comments from Lead Reviewer: TBD.

Scope: This memo covers aspects of ECG acquisition and processing and AF detection algorithm. Other aspects are not reviewed unless otherwise noted.

Note: this memo and deficiencies are intended for internal discussion only, and should not be communicated to the sponsor unless otherwise indicated. Minor edits can be made to the deficiencies, in case of doubt or major edits, please contact the consultant.
Color coding (unless otherwise specified): plain font my comment; *italics* quotes from the sponsor; highlight: red = inadequate, green = adequate, yellow=comment to the lead reviewer;

Summary/device description

TBD

Issues / analysis

- Unresolved anomalies – main de-novo section 8.11 – A discussion on unresolved anomalies was started with Apple by request of software consultant Dr. Yarkony; new data and narrative may be provided by the sponsor. Evaluation of this aspect is deferred to include the review of this additional information / clarifications.

(b) (4)

(b) (4)

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(b) (4)

(b) (4)

(b) (4)

Date: August 17, 2018

From: Xuan Ye, Ph.D., Mathematical Statistician
Arkendra De, Ph.D., Mathematical Statistician
Division of Biostatistics, OSB/CDRH

Subject: Statistical Review of DEN180044, (b) (4), by (b) (4).

To: Luke Ralston, Lead Reviewer
ODE\DCD\CDDB

Through: Lilly Yue, Ph.D., Deputy Division Director
Yunling Xu, Ph.D., Deputy Division Director
Ram Tiwari, Ph.D., Division Director
Division of Biostatistics, OSB/CDRH

CC: DBS Reviews

1. Proposed Indications for Use

(b)(4) Draft

2. Brief Description of the Device

(b) (4)

(b) (4)

(b) (4)

[redacted]

3. Clinical Validation Study

(b)(4) Test Data

[redacted]

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

4. Comments/Questions for the Review Team

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

MEMORANDUM

DATE: September 8, 2018
FROM: Linda Ricci
Associate Dir Digital Health, ODE

TO: DEN180044
ECG App(b) (4)

Linda J. Ricci -S
2018.09.08 12:18:34 -04'00'
Linda Ricci

I. INTRODUCTION

(b) (4)

The purpose of this memo is to document and assess the interactive review elements related to software, address the remaining software deficiencies identified by Dr. Yarkony and provide a final software assessment.

II. Remaining Deficiencies and Assessment

1. You provided a revised version of the Hazards analysis in appendix H. FDA reviewed the analysis and found it inadequate for the following reasons:

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

[redacted]

3. You provided software architecture in Appendix G. The software architecture provided still high-level and doesn't provide sufficient details on the components. (b) (4)

[redacted]

This is needed to allow FDA to assess the adequacy of the architecture. Please your software architecture to include the missing information.

(b) (4)

[redacted]

(b) (4)

[redacted]

4. You provided the Software Design Specification (SDS) in Appendix J. The provided document includes a summary of the functionality of different modules, and a sequence diagram. (b) (4)

[redacted]

(b) (4)

[redacted]

In order to allow FDA to assess the adequacy of the software design, please include information on how the software was designed.

(b) (4)

[redacted]

7. You included a description of the verification testing in section 8.9 software verification and validation in the main de-novo submission, you included appendix P with software verification, however you have not included validation testing or a reference to it in section 8.9. FDA reviewed the information that you provided and identified the following issues that should be addressed: (b) (4)

[redacted]

Please provide such test reports of an exact reference to them for review.

The sponsor acknowledged that it wasn't provided, and indicate that validation (not verification will be provided by 8/28). Both should be provided.

(b) (4)

[redacted]

III. Conclusion

As documented above, I believe that the sponsor has addressed all of the remaining software deficiencies and from a software perspective, the file can be granted.

(b)(5) Draft

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(b)(5) Draft

[redacted]

Human Factors (HF) Consult Memo

Consult Number:	CON1818576
Document Number:	(b) (4)
Applicant:	(b) (4)
Trade Name:	(b) (4)
Consult Type:	Human Factors
Requestor:	Luke Ralston [LTR] luke.ralston@fda.hhs.gov ; 301-796-6362
Requestor Home:	CDRH\ OHT2\ DHT2A\ THT2A3
Requested Consultant:	
Gatekeeper / Consultant:	Kimberly Kontson [KIMBERLY.KONTSON] kimberly.kontson@fda.hhs.gov ; 301-796-4990
Consultant Home:	CDRH\ OSEL\ DBP
Date Requested:	July 30, 2018
Due Date:	August 17, 2018
Instructions:	
Indications for use:	(b)(4) Draft [redacted]
Key considerations for conducting a HF review:	Q-SUB – Are there specific sponsor questions to be addressed?

Date consult sent: August 17, 2018

(b)(4) Test Data [redacted]

(b)(4) Test Data

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Ralston, Luke

From: De, Arkendra
Sent: Wednesday, August 29, 2018 4:59 PM
To: Ralston, Luke
Cc: Ye, Xuan; Yue, Lilly Q.; Xu, Yun-Ling
Subject: DEN180044: All of the Remaining Statistical Concerns

Luke,

Please see below for our remarks about the sponsor's responses (sent to FDA on August 28, 2018).

The sponsor adequately addressed the concerns raised in items 7, 9, 10, and 11. For items 5, 6, 8, and 12, the sponsor's responses raise additional concerns. Please see below for these concerns as well as other remaining concerns for the (b) (4) DeNovo submission.

Remaining Concerns:

(b) (4)

(b) (4)

[redacted]

Please consider the above as our only remaining and outstanding concerns for this submission.
If there are questions, please feel free to contact us.

Thanks,
Xuan and Arkendra

DEN180044

Day 45 Briefing

Sponsor: (b) (4) (Apple Inc.)

Device: (b) (4)

Agenda

- Device description and proposed indications for use
- Relevant regulatory history
- Classification summary (De Novo eligibility analysis) – Network of Experts
- Summary of all supporting data (non-clinical and clinical)
- Summary of any major concerns/anticipated deficiencies
- Draft Risk/Mitigation Table
- Draft special controls
- Draft regulation (name, identification, and number)

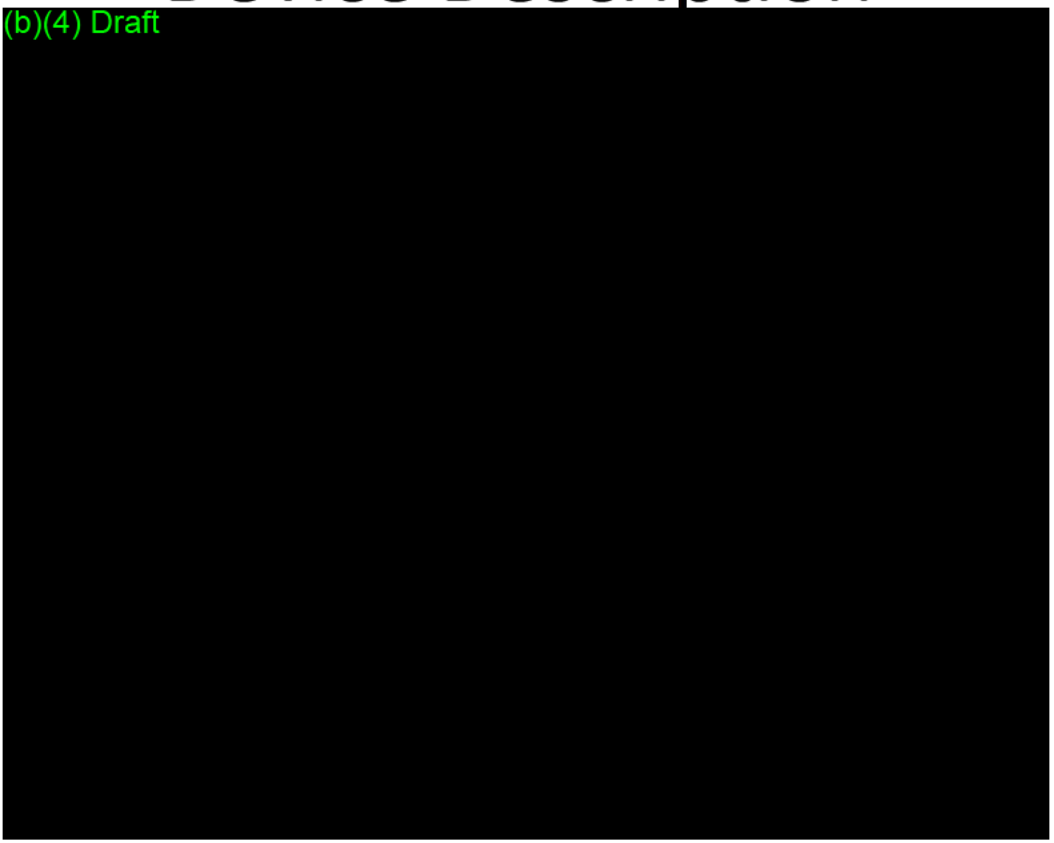
Device Description

(b)(4) Draft

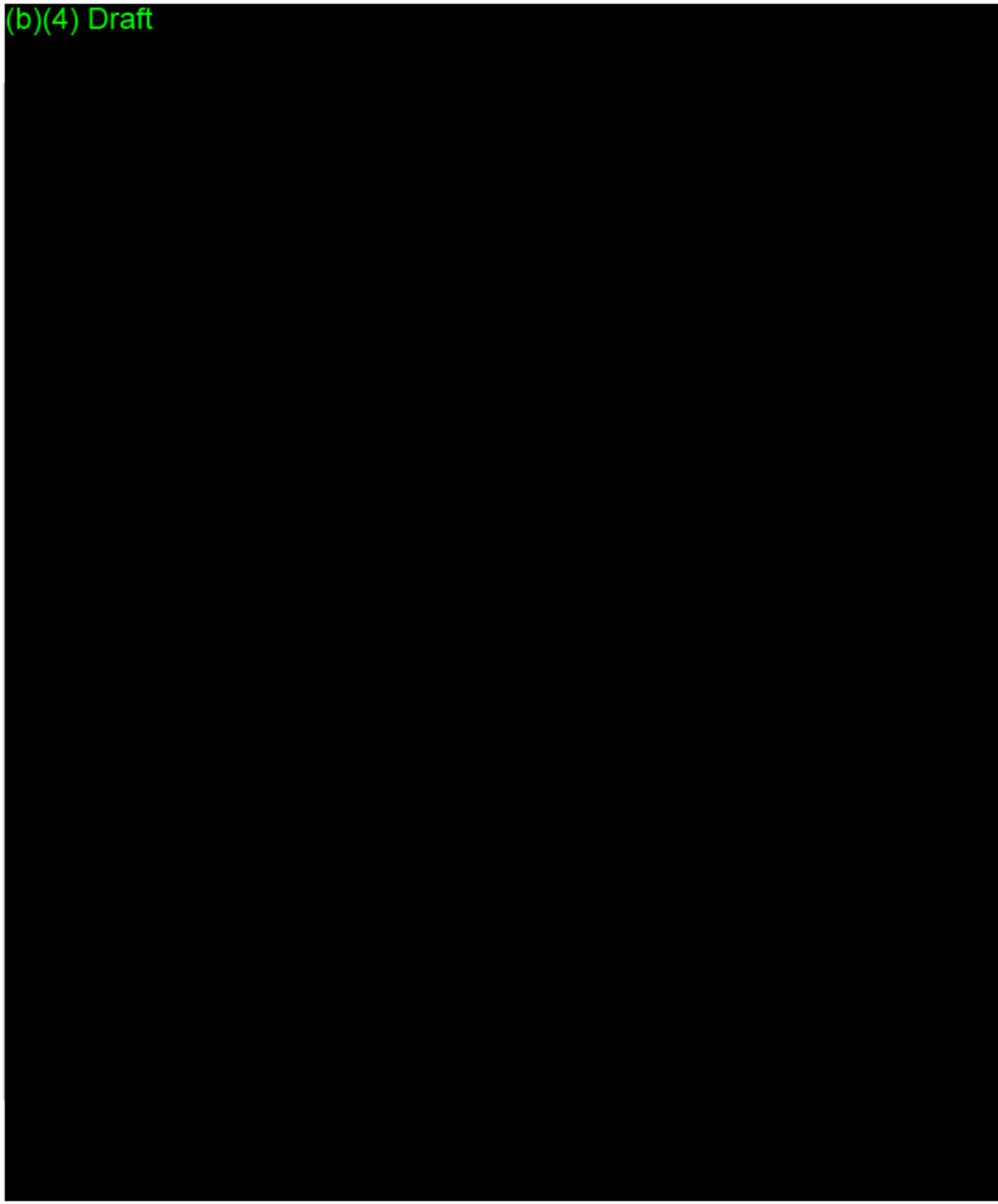
(b)(4) Draft

Device Description

(b)(4) Draft



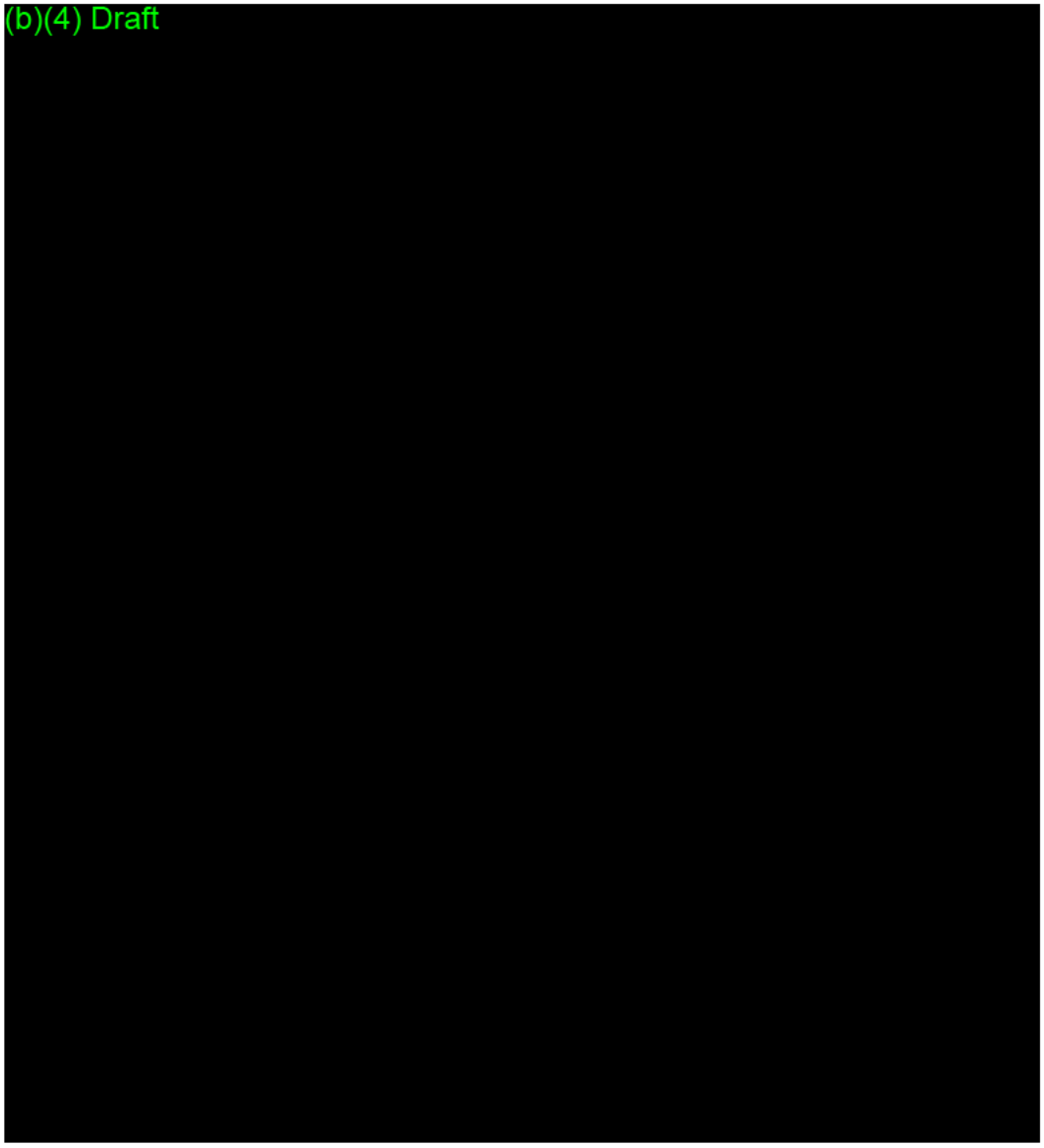
(b)(4) Draft



Device Description

(b)(4) Draft

(b)(4) Draft



Proposed Indications for Use

(b)(4) Draft

Regulatory History

- FDA has restricted display of ECG recordings to Rx only. To date, no device has been able to provide adequate directions for use to enable lay use for OTC ECG interpretation (per FD&C 502(f)(1) and 21 CFR 801.109).
- 5 previous Q-submissions were submitted by the sponsor to gain FDA feedback. (Refer to handout with Background summaries).
- The sponsor made several changes to the statistical protocol, clinical protocol, and user interface as late as June 2018.

Regulatory History – Network of Experts

- 2 of the 3 consulted cardiologists believe that false negatives are the primary concern – that 'false sense of security' from device will eclipse symptoms. This is supported by the HF results.
- All 3 advocate that sensitivity and PPV must be as high as possible, generally above 95% but PPV even as high as 99%
- 2 of 3 expressed serious concerns about data management and how rhythms would be conveyed to physician for confirmation – i.e. time needed to confirm/disconfirm hundreds or thousands of readings
- Opinions differed about the risk associated with false positives in part because the new OTC population will have a range of responses

Regulatory History

- The CDRH Digital Health team had several interactions with Apple outside the scope of this review and has attempted to exempt the Watch and iPhone from FDA review. This would severely limit our ability to require even basic performance data from similar manufacturers in the future.
- This review team has determined that the ECG acquisition hardware is subject to FDA regulatory oversight
- In addition, the only records of previous discussions were in regards to a PPG-based algorithm and do no pertain to the Spice App
- Apple has subsequently submitted limited design and performance specifications of the Watch for FDA review

De Novo Eligibility

- The FDA database was searched for any and all Electrocardiographs (ECG) with Over-the-Counter (OTC) use. There have been no devices cleared for OTC use. There were 7 results for combination Rx/OTC device manufactured by AliveCor, Inc. – the AliveCor Heart monitor and the AliveCor Kardia Band.
- An OTC-only ECG has new intended use and dramatically different intended user population. The new indication also raises new questions of safety and effectiveness because of the training and experience needed to interpret basic ECG parameters
- When combined with arrhythmia detection, the sponsor must demonstrate adequate mitigation of false positives and false negatives

Summary of Supporting Data

- Human Factors
- Clinical
- Statistical
- EMC/EMI
- Bench Test and algorithm performance
- Software

Device Versions Used Throughout Testing

Test	Algorithm Version	App (UI) Version
CV Study	(b) (4)	
HFE		
Database Testing (included in Appendix V)		
Verification Testing (QA)		
Subject Device		

Human Factors

Critical task related to user understanding the limitations of the App: "When, if ever, will this App detect a heart attack, blood clot, stroke, or other heart-related issue?"

- 6 out of 50 participants encountered a use error

(b) (4)

Human Factors

Critical tasks related to seeking emergency medical care after receiving Sinus Rhythm, AF, and Inconclusive notifications while experiencing acute symptoms were performed

- 9 out of 50 participants encountered a use error when comparing responses to baseline actions

(b) (4)

(b) (4)

Clinical

- The clinical study (CV Study) was the primary method intended to validate device performance.

(b)(4) Test Data

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Software

- Software requirements are incomplete and do not map to hazard analysis or resultant verification testing. In several instances a software requirement was changed or deleted as the result of a failed test case
- The information provided in the hazard analysis tables is high level and is missing key elements necessary to adequately identify control measures and test them.
- Several critical hazards don't include validation of the identified mitigation measures. Of major concern is the lack of validation for the controls related to the platform (Watch) requirements.

Software

(b) (4)

The review team is still attempting to resolve some issues interactively.

MAJOR CONCERNS

1. No validation of the final finished device has been submitted
2. The ECG function has not been validated – required to support IFU
3. Excluded data: (b) (4) [redacted]
4. There are systemic and fundamental deficiencies with all of the basic software documentation. (b) (4) [redacted]
5. Enrollment in the CV study (b) (4) [redacted] It is unknown if this data can be applied to the general population for OTC use.

MAJOR CONCERNS

6. Major remaining statistical concerns including reusing data, prevalence estimates, and interim data analysis must be resolved before approval.

7. HF results indicate an overreliance on the output of the technology to tell them when they should be concerned about symptoms they are experiencing.

8. The sponsor has not identified the hazard of EMI around frequencies other than powerline frequencies during ECG transmission

9. The True Positive and True Negative results calculated by FDA are much closer to the performance demonstrated during EC57 database testing – 81% vs. 81.6%

DRAFT Risks to Health and Mitigations

(b) (4)

DRAFT Regulation

(b) (4)

U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/ODE/DCD/CDDB
WO66 RM1311 HFZ-450
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6362

De Novo Review

Date: September 4, 2018

Reviewer: Luke Ralston

Subject: Direct De Novo # DEN180044

Applicant: (b) (4)

Contact Name: Donna-Bea Tillman

Correspondent Firm: Biologics Consulting Group, Inc.

Received Date: 08/14/2018

Reg #:

Pro Code(s):

Device Trade Name: (b) (4)

Contact Title: Senior Consultant, Biologics Consulting Group

Phone: (410) 531-6542 **Email:** dtillman@biologicsconsulting.com

Due Date: 10/28/2018

Reg Name:

Class: [Choose] **510k Exempt Yes/No** [Choose]

Post-NSE 510k :

Submission #	Pro Code	Device Trade Name	Applicant

Recommendation

I recommend that the De Novo request for the (b) (4) is declined (DEND)

Review Summary

(b) (4), (b) (5)

[redacted]

(b) (4), (b) (5)

(b) (4), (b) (5)

[redacted]

The remaining major deficiencies are:

(b) (5)

[redacted]

Review Team

Lead Reviewer	Luke Ralston (CDRH/ODE/DCD/CDDB)
Electrophysiology	Loriano Galeotti, Ph.D. (CDRH/ODE/DCD/CDDB)
Statistics	Xuan Ye, Ph.D. (CDRH/OSB/DBS)
Statistics	Arkendra De, Ph.D. (CDRH/OSB/DBS)
Clinical	Kan Fang, M.D. (CDRH/ODE/DCD/CEDB)
Software	Nathalie Yarkony Ph.D. (CDRH/ODE/DCD/CEDB)
De Novo Policy	Peter Yang, Ph.D. (CDRH/ODE)
Human Factors	Kimberly Kontson (CDRH/ODE/DAGRID/HFMET)
EMC/EMI	Aneesh Deoras (CDRH/ODE/DCD/CEMB)

I. Background, Submission Summary and De Novo Eligibility

(b) (5), (b) (4)

[redacted]

(b) (5), (b) (4)

(b) (5), (b) (4)

(b) (5), (b) (4)

De Novo Eligibility	
What is the sponsor's recommended classification for the subject device?	Class II
Do you wish to conduct a De Novo eligibility review for this device (required for originals)?	Yes Undo

De Novo Eligibility Information Red = Unanswered or Potential Eligibility Issue

Product meets the definition of a medical device: Yes

Device could be classified under an existing class I/class II regulation: No

A class III regulation exists for this device type: No

An approved PMA exists for this device type: No

Based on the responses to the first four questions above, this product appears to be eligible for De Novo review. The next questions will elicit any content-related issues.

This is a bundled submission: No

Device is a combination product or presents jurisdictional issues: N - Not a Part 3 Combination Product

Device is a candidate for enforcement discretion: No

Device is or includes a Mobile Medical App (MMA), stand-alone software-only product, and/or software as a medical device: Yes

Submitter is requesting review under the Breakthrough Devices (formerly EAP) designation process: No

(b) (5)

[redacted]

Sufficient information has been provided to allow a substantive review: Yes

De Novo review can proceed.

(b) (5), (b) (4)

[redacted]

(b) (5), (b) (4)

DEN180044, Spice De Novo

Indications for Use Comparison	
Spice (DEN180044, Q172032)	KardiaBand (K171816)
(b)(4) Draft	The KardiaBand System is intended to record, store and transfer single-channel electrocardiogram (EKG) rhythms. The KardiaBand System also displays EKG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The KardiaBand System is intended for use by healthcare professionals, adult patients with known or suspected heart conditions and health conscious individuals.

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

[redacted]

TPLC Information

II. Device/System Description

Is this device eligible for De Novo?	Yes	Undo

Device Description Information	Red = Inadequate or Unanswered	Yellow = Marked
Device is life-supporting or sustaining: No		
There are direct/indirect patient contacting components: Yes		
• **Device or a component is an implant:** No		
Device uses software/firmware: Yes		
• **Device is or contains Digital Health technology:** Yes		
• **Connection Types:** Cloud, Network, Wireless, Software upgrades		
Device or component needs sterilization: No		
Use/Reuse information: Reusable single patient use		
Environments of Use: Professional Healthcare Facility, Home, Other		
Combination Product Type: N - Not a Part 3 Combination Product		
The Device/System is electrical: Yes, it is battery powered Only		
• **Wireless Technology is used:** Yes		
Device Attributes		
Nanotechnology present: No		

Device Description Information	Red = Inadequate or Unanswered	Yellow = Marked
Companion Diagnostic: No		
Medical Counter Measures: No		

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

[redacted]

Reviewer Recommendation

The Device Description, including technology description, is minimally acceptable.

(b) (5)

[redacted]

III. Indications for Use

Indications for Use

Subject

De Novo #: DEN180044 Rx/OTC: OTC

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☒	☐	☐	☐	☐	☐	☐	☐
No	☐	☒	☒	☒	☒	☒	☒	☒
Unknown	☐	☐	☐	☐	☐	☐	☐	☐

Indications for Use: (b) (4)

[redacted]

Indications for Use

(b) (4)

(b) (4), (b) (5)

Reviewer Recommendation

The Indications for Use are **not** acceptable.

(b) (4), (b) (5)

(b) (4), (b) (5)

[redacted]

IV. Labeling

Labeling Review Needed?	**Yes**	Undo
Usability Consult Needed?	Yes	No

(b) (5)

[redacted]

Reviewer Recommendation

The Labeling is **not** acceptable.

V. Reprocessing, Sterilization, and Shelf-Life

Not applicable.

Reviewer Recommendation

Cleaning, Sterilization, Shelf-Life and Reuse descriptions are acceptable.

VI. Biocompatibility

Biocompatibility Review Needed?	Undo	No
Biocompatibility Consult Needed?	Yes	No

Not applicable.

Reviewer Recommendation

The Biocompatibility information is acceptable.

VII. Software/Firmware & Cybersecurity/Interoperability

Software Review Needed?	Yes	No	Cybersecurity/Interoperability Review Needed?	Yes	No
Software Consult Needed?	Yes	No	Cybersecurity/Interoperability Consult Needed?	Yes	No

(b) (4), (b) (5)

[redacted]

(b) (4), (b) (5)

(b) (4), (b) (5)

[redacted]

Reviewer Recommendation

The Software is **not** acceptable.

VIII. EMC, Wireless, Electrical, Mechanical and Thermal Safety & Risk Analysis

EMC Review Needed?	Yes	No	Wireless Review Needed?	Yes	No
EMC Consult Needed?	Yes	No	Wireless Consult Needed?	Yes	No

(b) (4), (b) (5)

[redacted]

Reviewer Recommendation

The EMC, Wireless, EMT and Risk Analysis are **not** acceptable.

IX. Performance Testing

(b) (4), (b) (5)

[redacted]

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

[redacted]

Reviewer Recommendation

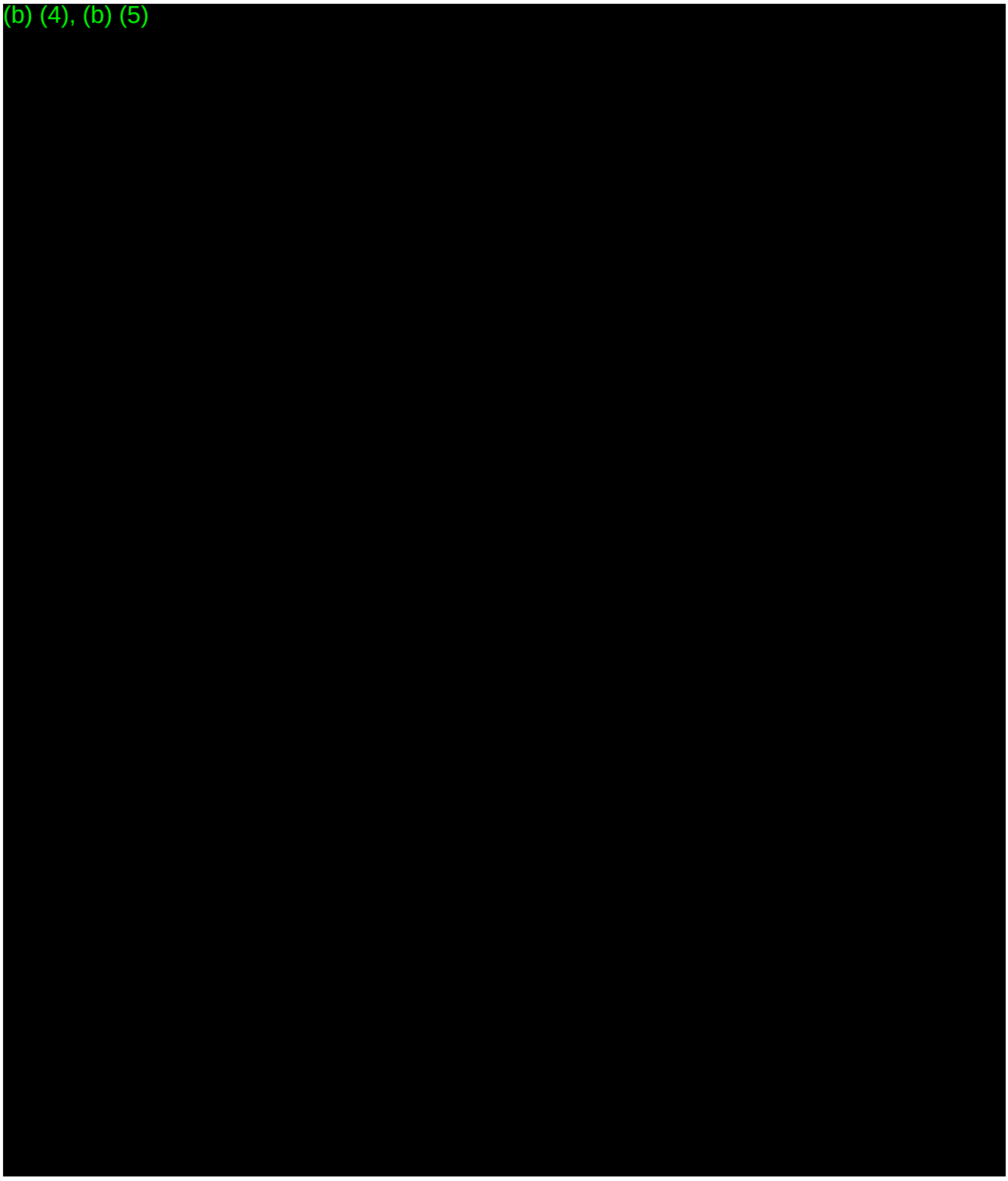
(b) (4), (b) (5)

[redacted]

The Performance Testing is **not acceptable**.

X. Special/General Controls Information

(b) (4), (b) (5)



(b) (4), (b) (5)

[redacted]

XI. Classification Discussion

This section must be completed only when granting the De Novo. However, pertinent information (e.g. discussion of sponsor's proposed classification) can be included at any time.

Regulation Identification

FDA identifies this type of device as: Electrocardiograph for Over-the-Counter Use with or without Arrhythmia Detection. An over-the-counter electrocardiograph with arrhythmia detection acquires, analyzes, and displays ECG data and can provide diagnostic information for identifying cardiac arrhythmias.

Exemption from 510(k)

Reviewer Recommendation

The Classification Discussion, Identification and Exemption from 510(k) are **[not]** acceptable.

XII. Benefit/Risk Assessment

See Attachment 3.a to this memo.

a. Patient Perspectives

XIII. Summary of Meetings

XIV. References

(b) (4), (b) (5)

[redacted]

(b) (4), (b) (5)

XV. Original Major Deficiencies

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

[redacted]

XVII. Original Additional Considerations

XVIII. Contact History

- 8-17-18 – Clinical report
- 8/15/2018 - Spice Hazard Analysis
- 8/15/2018 - HFE Results
- 8/16/2018 - Send FDA slide deck from Interactive Review Meeting 8/16
- 8/16/2018 – Unresolved Anomalies
- 8/16/2018 – Hazard Analysis – Labeling
- 8/16/2018 – Platform Requirements
- 8/16/2018 – SW Documentation Review for Inconsistencies
- 8/17/2018 – Clinical data questions
- 8/23/2018 - High/Low HR
- 8/21/2018 – Excluded ECG strips
- 8/22/2018 – Software questions
- 8/24/2018 – Clinical Issues
- 8/24/2018 – Platform validation, Statistical justifications, and performance testing
- 8/28/2018 – Responses to FDA's 8/24 requests
- 8/29/2019 – Responses to Platform Input signal testing request

Digital Signature Concurrence Table (Doc#: 04025.01.10)	
Reviewer Sign-Off	Luke T. Ralston -S 2018.09.04 15:36:39 -04'00'

Attachments

1. Electrophysiology memo from Loriano Galeotti, Ph.D.
2. Statistics memo from Xuan Ye, Ph.D. and Arkendra De, Ph.D.
3. Clinical review memo and Benefit/Risk Assessment from Kan Fang, M.D.
4. Software review memo from Nathalie Yarkony Ph.D.
5. Human Factors memo from Kimberly Kontson
6. EMC/EMI memo from Aneesh Deoras
7. Network of Experts transcript – Dr. Upadhyay
8. Network of Experts transcript – Dr. DiBiase
9. Network of Experts transcript – Dr. Lakkireddy

DEN180044 – (b) (4) (Apple) – (b) (4)

Date: Tuesday, September 04, 2018

Consultant: Loriano Galeotti, PhD
(FDA / CDRH / Office of Device Evaluation / Division of Cardiovascular Devices / Cardiac Diagnostic Devices)

Lead reviewer: Luke Ralston.

Instructions/comments from Lead Reviewer: TBD.

Scope: This memo covers engineering related to of ECG acquisition and processing and AF detection algorithm. Other aspects are not reviewed unless otherwise noted.

Note: this memo and deficiencies are intended for internal discussion only, and should not be communicated to the sponsor unless otherwise indicated. Minor edits can be made to the deficiencies, in case of doubt or major edits, please contact the consultant.
Color coding (unless otherwise specified): plain font my comment; *italics* quotes from the sponsor;
highlight: red = inadequate, green = adequate, yellow=comment to the lead reviewer;
When referencing "this" submission, I'm meaning the current submission under review as indicated in the header of the present document, unless otherwise specified.

Outstanding deficiencies are denoted by highlighted red font while deficiencies that were previously communicated to the sponsor are in red.

Summary/device description

Indications for use

(b)(4) Draft

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

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(b) (4), (b) (5)

(b) (4), (b) (5)

Date: August 17, 2018

From: Xuan Ye, Ph.D., Mathematical Statistician
Arkendra De, Ph.D., Mathematical Statistician
Division of Biostatistics, OSB/CDRH

Xuan Ye -S Digitally signed by Xuan Ye -S Date: 2018.08.20 16:38:32 -04'00'

Arkendra K. De -S

Subject: Statistical Review of DEN180044, (b) App, by (b) (4)

To: Luke Ralston, Lead Reviewer
ODE\DCD\CDDB

Through: Lilly Yue, Ph.D., Deputy Division Director
Yunling Xu, Ph.D., Deputy Division Director
Ram Tiwari, Ph.D., Division Director
Division of Biostatistics, OSB/CDRH

Lilly Q. Yue -S Digitally signed by Lilly Q. Yue -S Date: 2018.08.20 16:58 40 -04'00'

Yunling Xu -S

CC: DBS Reviews

1. Proposed Indications for Use

(b)(4) Draft

[redacted]

2. Brief Description of the Device

(b)(4) Draft

[redacted]

(b)(4) Test Data

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FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

[redacted]

OFFICE OF DEVICE EVALUATION
De Novo CLINICAL REVIEW

Date:	August 18, 2018	**Branch:**	CDDB
To:	Luke Ralston, Lead reviewer	**Division:**	DCD
From:	Kan Fang, MD. CDRH/ODE/DCD/CEDB		
cc:	Jessica Paulsen, Branch chief, IEDB		
	Mark Fellman, Branch chief, CEDB		
File:	DEN180044		
Purpose:	Clinical Review Memo		
Applicant:	(b) (4)		
Device/Study:	(b) App		

Recommendation: Additional Information

(b) (4), (b) (5)

[redacted]

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(b)(5) FDA Draft

(b)(5) FDA Draft

(b)(5) FDA Draft

(b)(5) FDA Draft

Level of Evidence Questions for Benefit-Risk Assessment

Form

Applies To: ODE and OIR

Date Effective: 06/20/2018

Use FEEDBACK✓CDRH to provide comments on this document (include Doc # 01126)

Purpose: This form is intended to serve as a complementary form to the Benefit-Risk Decision Support Tool to guide review staff regarding critical elements that should be considered as part of the thought-process associated with benefit-risk assessments. This form is intended for inclusion as part of the administrative record and also intended to facilitate management's review during the oversight process in order to ascertain which elements were considered by review staff.

Instructions: Consider questions 1-8 for Column A (the proposed Indication for Use), until you reach a recommendation to either approve/grant or move to Column B. When considering an acceptable, modified Indications for Use, interact with the sponsor to reach agreement on a modified Indication for Use.

Beta Testing Instructions: Send feedback concerning any issue identified as a result of using the revised B-R tools to Benefit-RiskTools@fda.hhs.gov. Upon completion of this form and the Decision Support Tool (when the documents are used as part of a management interim meeting or for supporting a final decision), email the completed documents to Benefit-RiskTools@fda.hhs.gov. Please note that Benefit-RiskTools@fda.hhs.gov is an internal email address for the purpose of the beta testing. Do not disseminate outside of CDRH.

Premarket Submission Type	☐ PMA ☒ De Novo
PMA/De Novo Number:	DEN180044
Device Name:	(b) App
Applicant:	(b) (4)
Medical Officer:	Kan Fang, MD
Scientific Reviewer:	Luke Ralston
Worksheet Completion Date:	August 31, 2018
Review Stage:	☐ Interim (Complete Q1-4, select considerations, and explain in text boxes. There is no need to answer Yes/No for Q5-8.) ☒ Final (Complete Q1-5 and Q6-8, as needed.)
Device Description:	

(b)(4) Draft

(b)(4) Draft

[redacted]

Proposed Indication for Use (IFU) – Column A:

(b)(4) Draft

[redacted]

Assessment of Benefit

1. **Is there any evidence of clinical benefit?**

   Is a clinical benefit demonstrated for the device for this indication (e.g., from any one or more of the primary and/or secondary datasets or from associated real-world evidence)? Benefit may be considered in terms of how a patient feels, functions, survives, or an acceptable surrogate outcome. Benefit may also be considered in terms of convenience in managing or diagnosing a disease or condition. Benefit should be considered based on the clinical assessment of the data, whether or not the results are statistically significant. *Select any of the following that demonstrate benefit.*

A	B	A favorable change in at least 1 clinical assessment that:
☐	☐	Is equal to or greater than seen in the control group
☒	☐	Meets a predetermined performance goal
☐	☐	Meets or surpasses a minimally important clinical difference
☒	☐	Is equal to or greater than seen with other available modalities for the condition
☐	☐	Would be meaningful to patients considering the severity, chronicity, etc., of the condition, taking into consideration patient-reported outcomes and health-related quality of life

☐ ☐ A favorable change in non-clinical data or modeling that is deemed to be predictive of clinical outcomes

☒ ☐ A favorable clinical performance characteristic (e.g., sensitivity/PPA,[1] specificity/NPA[2], etc.) for the screening, diagnosis, prognosis, monitoring or treatment selection

☐ ☐ Acceptable performance characteristics for analytical validation of the device

☐ ☐ Other(s) Click here to list other(s)

☐ ☐ None

Q1: Is there any evidence of clinical benefit?

A B

☒ ☐ YES → Continue to Question 2

☐ ☐ NO → Move one column to the right (or, if final column has been reached and you have determined there is no evidence of clinical benefit, do not approve the application/request)

[1] PPA: Positive Percent Agreement

[2] NPA: Negative Percent Agreement

2. What is the degree of uncertainty for the benefits?

Recognizing that some degree of uncertainty always exists, select the sources of uncertainty, if applicable, in the data that affect your assessment of the clinical benefit. Consider sensitivity, specificity, accuracy, precision, reproducibility, etc. (analytical and/or clinical validation, as applicable).

A B

☐ ☐ Inconsistent or conflicting results between studies
☐ ☐ Wide confidence intervals surrounding the point estimate(s) and/or odds ratio(s))
☐ ☐ A significantly underpowered study with statistical insignificance in outcome measure(s)
☐ ☐ High subject or specimen loss-to-follow-up at critical assessment point(s)
☐ ☐ Large amount of missing data at critical assessment time(s) +/- imputation
☐ ☐ Significant number of major protocol deviations
☐ ☐ Impact of confounding interventions or physiological factors
☐ ☐ Inconsistent user experience or user experience not representative of likely real world user
☒ ☐ Unclear correlation between pre-selected enriched data and clinical performance
☐ ☐ Surrogate endpoint has not yet been demonstrated to correlate with a clinical outcome
☐ ☐ Real World Evidence (RWE) is not relevant or reliable for the purposes of the proposed analysis
☐ ☐ Inspectional findings
☒ ☐ Study design or results lead to lack of generalizability for the intended use population or specific clinical subpopulations.
☐ ☐ Physiological or clinically meaningful range of the diagnostic output is unknown or generalizability of proposed clinical cut-off is unknown
☐ ☐ Imperfect comparator method used to calculate performance characteristics
☐ ☐ Other(s) Click here to list other(s)
☐ ☐ None

Q2: What is the degree of uncertainty for the benefits?

A B

☐ ☐ Low → Continue to Question 3
☒ ☐ Med → Continue to Question 3
☐ ☐ High → Continue to Question 3

Summary of the Assessment of Benefit

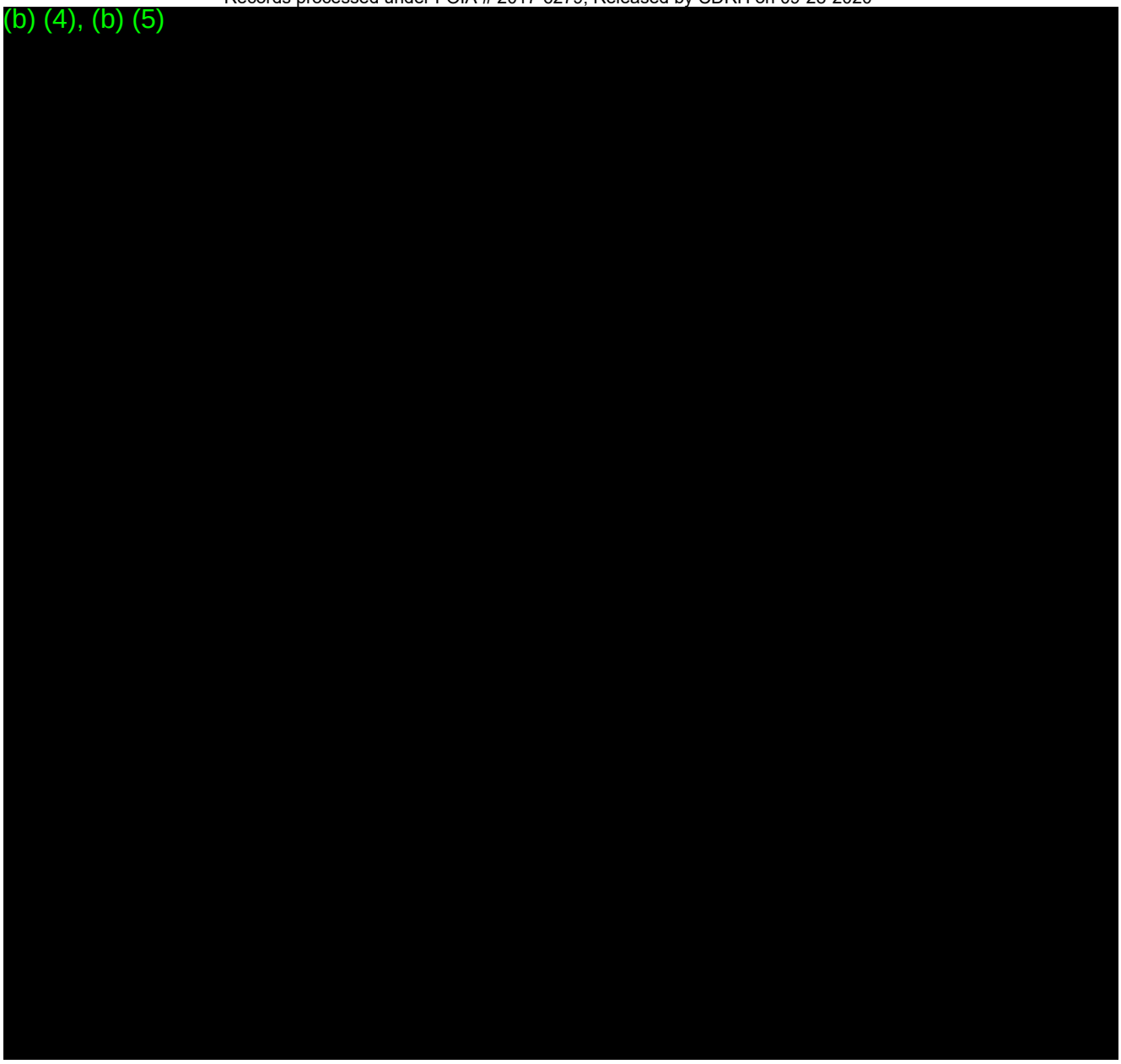
For the Proposed Indications for Use (Column A):

The Spice app has two different intended uses, and each use will be considered separately.

(b) (4), (b) (5)

[redacted]

(b) (4), (b) (5)



Assessment of Risk

3. Are known/probable risks more than minimal?

Select the elements that apply for known/probable risks that are more than minimal.

A	B	
☐	☐	Adverse events (AEs) or outcomes related to the device itself
☐	☐	AEs or outcomes related to the use of the device or procedure to use the device
☐	☐	AEs or outcomes related to anesthesia or sedation to use the device
☐	☐	AEs or outcomes due to subsequent tests/treatments needed (e.g., radiation from CT scans)
☐	☐	AEs or outcomes, not seen in the study/data, but probable based on "class effect" or events known to occur with similar technologies
☒	☐	False positive/false negative/failed to provide a result for diagnostics
☐	☐	Treatment or diagnostic intended to be used as a standalone rather than an adjunctive use
☐	☐	Other(s) [Click here to list other(s)]
☐	☐	None

Q3: Are known/probable risks more than minimal?

A	B	
☐	☐	YES → Continue to Question 4
☒	☐	NO → Continue to Question 4

4. What is the degree of uncertainty for the risks?

Recognizing that some degree of uncertainty always exists, select the sources uncertainty, if applicable, in the data regarding the adverse events/outcomes or risks.

A	B	
☐	☐	Insufficient patient numbers to detect serious events or false positives/false negatives
☐	☐	Insufficient duration of follow-up to detect delayed/late events
☒	☐	Lack of data on repeated exposure to the device/use
☐	☐	Inconsistent or conflicting results between studies
☐	☐	Proper evaluations not performed as part of the study protocol to adequately detect certain AEs
☐	☐	Poor or inconsistent adverse event definitions and documentation
☐	☐	Events likely confounded by, and attributed to, other comorbidities or treatment modalities
☐	☐	High subject loss-to-follow-up at critical assessment point(s)
☐	☐	Large amount of missing data at critical assessment time(s) +/- imputation
☐	☐	Significant number of major protocol deviations
☐	☐	Inconsistent user experience or user experience not representative of likely real world user
☒	☐	Concerns related to performance characteristics (e.g., sensitivity/PPA, specificity/NPA)
☐	☐	Imperfect comparator method used to calculate performance characteristics
☐	☐	Other(s) Click here to list other(s)
☐	☐	None

Q4: What is the degree of uncertainty for the risks?

A	B	
☒	☐	Low → Continue to Question 5
☐	☐	Med → Continue to Question 5
☐	☐	High → Continue to Question 5

Summary of the Assessment of Risk

For the Proposed Indications for Use (Column A):

To record, store, transfer, and display Lead I ECG signals

Type of Risk

The device does not cause direct physical harms.

(b) (4), (b) (5)

[redacted]

(b) (4), (b) (5)

[redacted]

Detection of atrial fibrillation or regular rhythm

The device is for diagnostic purpose and does not cause direct physical harms. The risks for harms are all related to false positive or false negative results

(b) (4), (b) (5)

[redacted]

Assessment of Benefit-Risk

At interim stage, it is not necessary to select "yes" or "no" for questions 5-8. Select the relevant considerations and explain in text boxes.

To approve a PMA application or grant a De Novo Request, FDA must find, among other things, that the device is reasonably safe and effective. FDA determines whether there is a reasonable assurance of safety and effectiveness by weighing any probable benefit to health from the use of the device against any probable risk of injury or illness for such use, among other relevant factors.

5. **Do the Benefits outweigh the Risks, considering the assessment of Benefit and Risk and the degrees of uncertainty identified above?**

A B

☒ ☐ Yes – the benefits outweigh the risks such that, for this device, additional consideration of relevant factors would not change that determination – approve/grant

☐ ☐ Undetermined – the benefits may not outweigh the risks, and further discussion and consideration of relevant factors is appropriate – Move to Q6

Summary of the Assessment of Benefit-Risk

For the Proposed Indications for Use (Column A):

(b) (4), (b) (5)

[redacted]

Kan D. Fang -S

Digitally signed by Kan D Fang -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Kan D Fang -S, 0.9.2342.19200300.100.1.1=20019296361
Date: 2018.08.31 10:07:17 -04'00'

MEMO OF

SOFTWARE REVIEW

of a Moderate Level of Concern device

De-Novo: DEN180044

(b) (4)

Date : August 29, 2018

To : Luke Ralston (CDRH/ODE/DCD/CDDB)

From : Nathalie Yarkony (CDRH/ODE/DCD/CDDB)

Sponsor : Apple

(b) (4)

Review Summary

(b) (4), (b) (5)

(b) (4), (b) (5)

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[redacted]

Human Factors (HF) Consult Memo

Consult Number: CON1819925
Document Number: DEN180044
Applicant: (b) (4)
Trade Name: (b) App
Consult Type: Human Factors
Requestor: Luke Ralston [LTR]
luke.ralston@fda.hhs.gov ; 301-796-6362
Requestor Home: CDRH\ OHT2\ DHT2A\ THT2A3
Requested Consultant:

Gatekeeper / Consultant: Kimberly Kontson [KIMBERLY.KONTSON]
kimberly.kontson@fda.hhs.gov ; 301-796-4990
Consultant Home: CDRH\ OSEL\ DBP
Date Requested: August 15, 2018
Due Date: August 20, 2018
Instructions:

Indications for use: (b)(4) Draft [redacted]

Key considerations for conducting a HF review: Is the supporting documentation adequate to demonstrate that the subject device UI supports safe & effective use?

Date consult sent: August 17, 2018

(b)(4) Test Data [redacted]

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U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

EMC/Electrical Safety Consult Memo

Date: 22 August 2018

To: Luke Ralston
CDRH/THT2A3

From: Aneesh Deoras
CDRH/THT2A2

Re: DEN180044 - CON1819926
(b) (4)
(b) (4)

Recommendation

Recommending one deficiency to address an inadequate EMC mitigation.

(b) (4), (b) (5)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

MEMORANDUM

DATE: September 11, 2018

FROM: Bram D. Zuckerman, MD
Director, Division of Cardiovascular Devices

TO: DEN180044 – ECG App (b)

RECOMMENDATION: GRANTED (GRNT)

Bram D. Zuckerman -S
2018.09.11 13:31:32 -04'00'
Bram . uc erman, MD

I. INTRODUCTION

The ECG App (previously referred to as (b) consists of 2 separate mobile medical apps—one on Apple Watch and the other on the iPhone. Using an electrical signal from the Apple Watch, the App creates an ECG waveform and displays the rhythm classification and an optional list of symptoms to be saved to session.

(b)(4) Draft

The regulatory history and review are well documented in the administrative file and summarized in Luke Ralston's Lead Review Memo, dated September 4, 2018. The reviewer has recommended a Decline (DEND) decision on the file.

On September 7, 2018, the sponsor amended the file to update (b) (4) Apple Inc. Additionally, the sponsor noted the change (b) (4) ECG App. This amendment was logged in while the file was undergoing management review and is not reflected in the lead reviewer's memo.

The purpose of this memo is to document the Division's management recommendation that the De Novo be GRANTED (GRNT).

II. REGULATORY HISTORY

The lead reviewer's memo documents a thorough and thoughtful assessment of the regulatory history and previous interactions with the sponsor regarding the App under review.

Based on CDRH policy, the Apple Watch is not considered within scope of this review given that there are no medical claims being proposed for the Watch. The Watch and the iPhone are considered general purpose computing platforms and therefore are not subject to FDA oversight. The Watch acquires an electrical signal from contact with the user, but the electrical signal itself does not have a medical claim. However, the ECG App that receives this electrical signal from the Watch and subsequently creates an ECG waveform (similar to a Lead I) does meet the definition of a device. Therefore, the ECG App is subject to FDA regulatory oversight.

III. REVIEW

The lead reviewer and his team have performed a rigorous scientific review and have concluded that the information provided in the De Novo submission and through subsequent interactions is not sufficient to establish a reasonable assurance of safety and effectiveness for the ECG App for its intended use. At the conclusion of the review, the following deficiencies were identified by the review team:

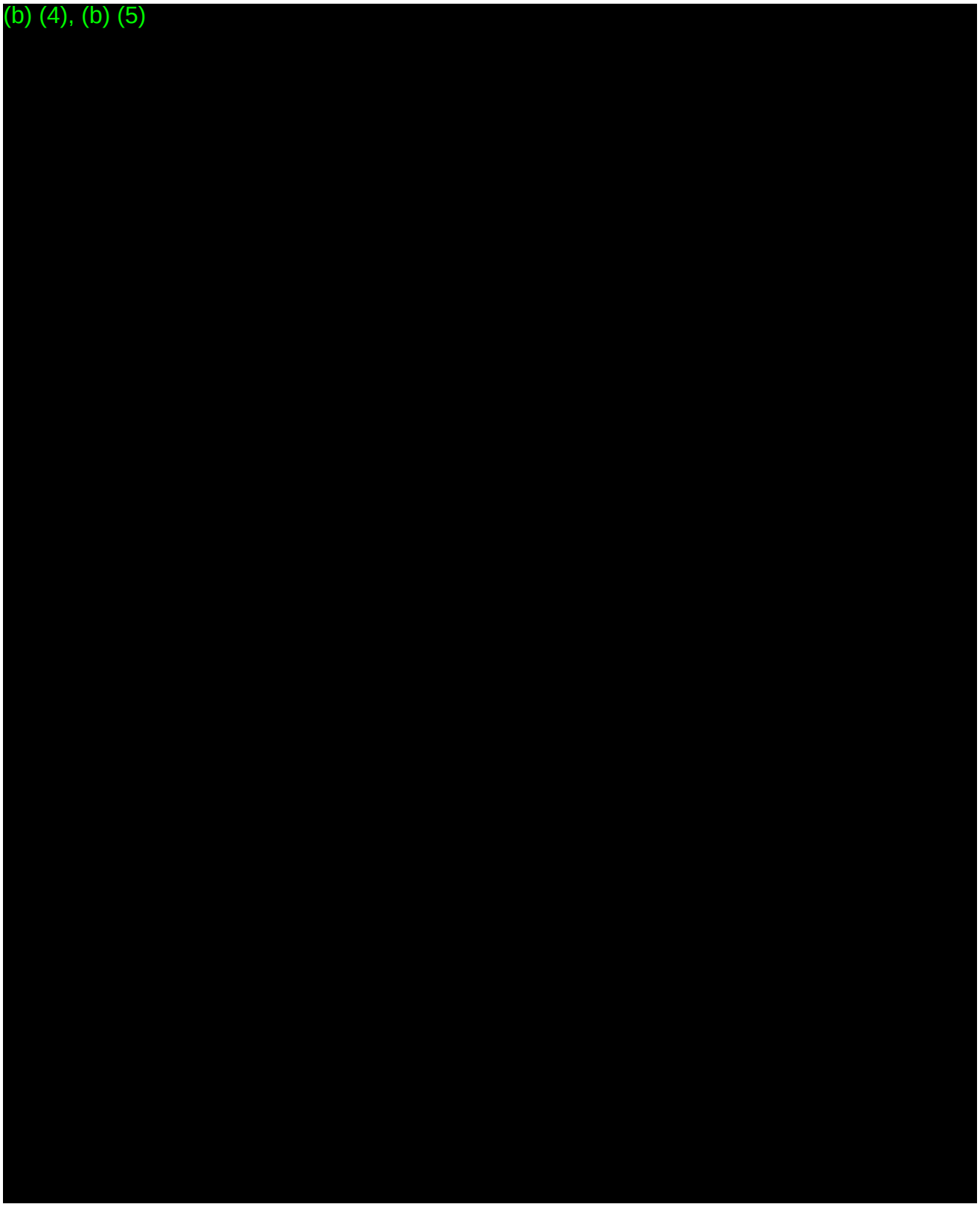
Device Description

(b) (4), (b) (5)

[redacted]

Labeling

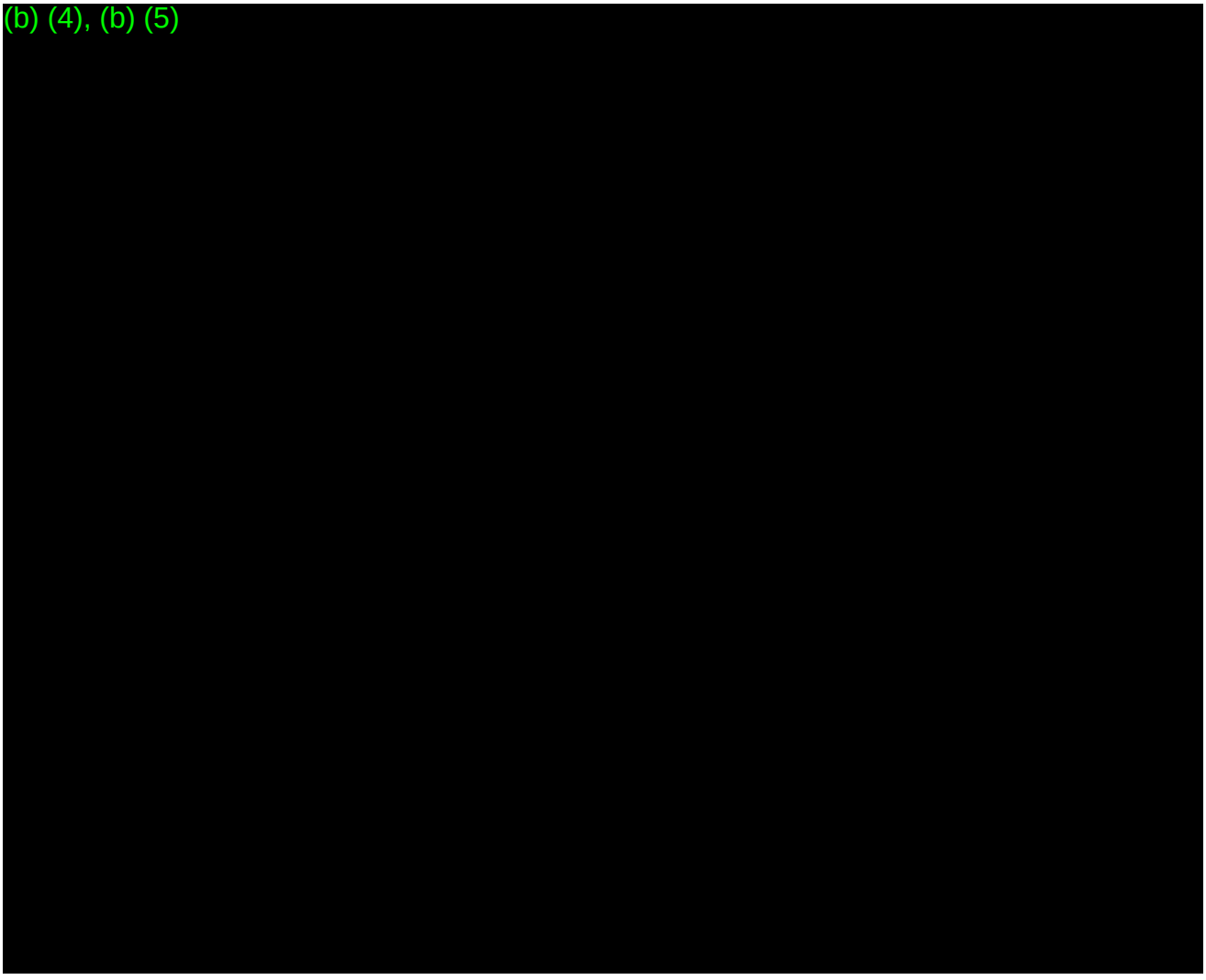
(b) (4), (b) (5)



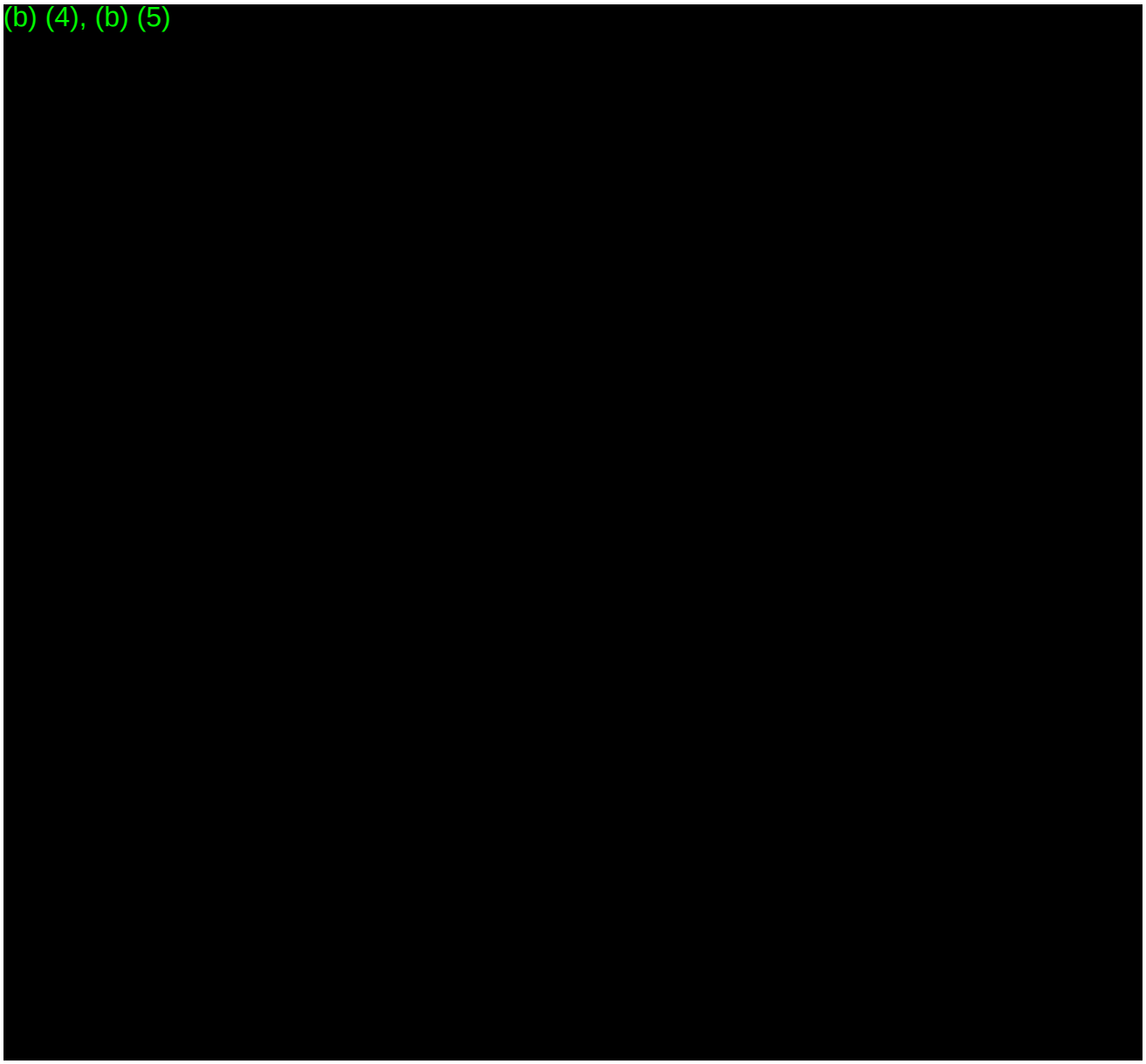
(b) (4), (b) (5)

Software, Cybersecurity and Interoperability

(b) (4), (b) (5)



(b) (4), (b) (5)



EMC, Wireless, and Electrical, Mechanical and Thermal Safety

(b) (4), (b) (5)

(b) (4), (b) (5)

Performance Testing

(b) (4), (b) (5)

Statistical

(b) (4), (b) (5)

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(b) (4), (b) (5)

[redacted]

IV. BENEFIT-RISK ASSESSMENT

Dr. Fang conducted the benefit-risk assessment for the proposed ECG App, which is well-captured in his memo and BR worksheet dated August 31, 2018. Overall, Dr. Fang concluded that there is reasonable assurance that the App is effective and safe as an ambulatory ECG recorder. For this intended use, he noted that there are minimal safety concerns. He believes the probable benefits of the device outweigh the risks when used by the intended population.

Dr. Fang recommended approval with the following:

- Recommended IFU revisions
- Post market study to evaluate the long-term performance of the device in the real world

(b) (4), (b) (5)

[redacted]

V. RECOMMENDATION

An extremely comprehensive and thorough review has been performed by Mr. Luke Ralston and his FDA review team. I believe, however, that the remaining deficiencies cited by Mr. Ralston have been adequately addressed.

As such I have concluded that the information provided by the sponsor demonstrates that there is a reasonable assurance of safety and effectiveness for the device for its intended use. I believe the benefits of the ECG App outweigh the risks, and I recommend this De Novo be granted.

(b)(5) FDA Draft

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ECG App

Instructions for Use

Apple Inc.
One Apple Park Way
Cupertino, CA 95014
www.apple.com

Revision [X]

[REVISION DATE]

INDICATIONS FOR USE

The ECG app is a software-only mobile medical application intended for use with the Apple Watch to create, record, store, transfer, and display a single channel electrocardiogram (ECG) similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (AFib) or sinus rhythm on a classifiable waveform. The ECG app is not recommended for users with other known arrhythmias.

The ECG app is intended for over-the-counter (OTC) use. The ECG data displayed by the ECG app is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from normal sinus rhythm and not intended to replace traditional methods of diagnosis or treatment.

The ECG app is not intended for use by people under 22 years old.

USING THE ECG APP

App Set-Up/On-boarding

- The ECG app is available on Apple Watch Series 4 with watchOS 5.1 or later, paired with iPhone 5s or later with iOS 12.1 or later.
- Open the Health app on your iPhone.
- In the Health Data tab, tap Heart, then select “Electrocardiograms.”
- Follow the onscreen instructions.
- You may exit on-boarding at any time by pressing “Cancel.”

Recording an ECG

- Make sure your Apple Watch is snug on the wrist you selected in Settings > General > Watch Orientation.
- Open the ECG app on your Apple Watch.
- Rest your arms on a table or in your lap, and hold your finger on the Digital Crown. You do not need to press the crown during the session.
- The recording takes 30 seconds.

ECG Analysis

- After a successful reading, you will receive one of the following classifications on your ECG app:
    - Sinus Rhythm: A sinus rhythm result means the heart is beating in a uniform pattern between 50-100 bpm.
    - Atrial Fibrillation: An AFib result means the heart is beating in an irregular pattern between 50-120.
    - Inconclusive: An inconclusive result means the recording can't be classified. This can happen for many reasons such as a high or low heart rate, not resting your arms on a table during a recording, or your Apple Watch is too loose. Certain physiological conditions may prevent a small percentage of users from creating enough signal to produce a good recording.
- After an ECG recording is complete, the ECG data is analyzed to determine if it is at least 25 seconds long, and, if so, if either Sinus Rhythm or AFib is present, or if an Inconclusive result is warranted.
- The ECG recording result on the ECG app provides a detailed display of the result. A detailed explanation will also be provided on your iPhone.
- Presence of AFib in your ECG results may represent only potential findings. If you are experiencing any symptoms or have concerns, contact your physician. If you believe you are experiencing a medical emergency, you should contact emergency services.
- A result of Sinus Rhythm means your heart rate is between 50 and 100 beats per minute and is beating in a uniform pattern.
- Inconclusive ECG results may mean that your heart rate was too high or too low for the app to classify the recording, there may have been too much artifact or noise to acquire a good signal, or you may have an arrhythmia other than AFib the app cannot classify. A small percentage of people may have certain physiological conditions preventing the user from creating enough signal to

produce a good recording. You can learn more about Inconclusive ECG results during on-boarding, by accessing educational information in the ECG area of the Health app on your iPhone, or by tapping the "i" icon on the ECG app for more information.

- If you receive an Inconclusive result due to a poor recording, you might try to re-record your ECG. You can review how to take an ECG during on-boarding or by tapping on "Take a Recording" in the ECG area of the Health app on your iPhone.
- All ECGs are synced to the Health app on your iPhone. You may use the Health app to share your ECG with a clinician.

SAFETY AND PERFORMANCE

The ECG app's ability to accurately classify an ECG recording into AFib and sinus rhythm was extensively tested in a clinical trial of approximately 600 subjects. Rhythm classification of a 12-lead ECG by a cardiologist was compared to the rhythm classification of a simultaneously collected ECG from the ECG app. The ECG app demonstrated 98.3% sensitivity in classifying AFib and 99.6% specificity in classifying sinus rhythm in classifiable recordings.

In this clinical trial, 12.2% of recordings were inconclusive and not classifiable as either sinus rhythm or AFib. When inconclusive recordings were included in the analysis, the ECG app correctly classified sinus rhythm in 90.5% of subjects with sinus rhythm and AFib in 85.2% of subjects with AFib.

The morphology of the waveform was also tested in this clinical trial by visual assessment of the PQRST wave and R wave amplitude in comparison to a reference. During this clinical trial, no adverse events were observed.

TROUBLESHOOTING

If you experience difficulties in operating your ECG app, refer to the troubleshooting guide below.

Problem: I cannot get the ECG app to take a reading.

Solution:

- Ensure that you have completed all of the on-boarding steps in the Health app on your iPhone.

- Make sure your wrist and your Apple Watch are clean and dry. Water and sweat can cause a poor recording.

- Ensure that your Apple Watch, arms, and hands remain still during recordings.

Problem: I have a lot of artifact, noise, or interference in my recording.

Solution:

- Rest your arms on a table or in your lap while you take a recording. Try to relax and not move too much.

- Make sure your Apple Watch isn't loose on your wrist. The band should be snug and the back of your Apple Watch needs be touching your wrist.

- Move away from any electronics that are plugged into an outlet to avoid electrical interference.

Problem: The ECG waveforms appear upside down.

Solution:

- The watch orientation may be set to the wrong wrist. On your iPhone, go to the Watch app. Tap My Watch > General > Watch Orientation.

All data recorded during an ECG app session is saved to Health app on your iPhone. If you choose to, you can share that Information by creating a PDF.

New ECG data cannot be recorded once your Apple Watch's storage is full. If you are not able to take a recording due to storage space issues, you should free up space by deleting unwanted apps, music or podcasts. You can check your storage usage by navigating to the Apple Watch app on your iPhone, clicking "My Watch", clicking "General", and then clicking "Usage".

CAUTIONS:

The ECG app cannot check for signs of a heart attack. If you believe you're having a medical emergency, call emergency services.

DO NOT take recordings when Apple Watch is in close vicinity to strong electromagnetic fields (e.g. electromagnetic anti-theft systems, metal detectors).

DO NOT take recordings during a medical procedure (e.g., magnetic resonance imaging, diathermy, lithotripsy, cautery and external defibrillation procedures).

DO NOT take recordings when Apple Watch is outside of the operational temperature range (0°C -35°C) indicated in the Apple Watch user manual and humidity range of 20% to 95% relative humidity.

DO NOT use to diagnose heart-related conditions.

DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.

DO NOT take a recording during physical activity.

DO NOT change your medication without talking to your doctor.

Not intended for use by individuals under age 22.

You should talk to your doctor if your heart rate is under 50 or over 120 at rest and this is an unexpected result.

Interpretations made by this app are potential findings, not a complete diagnosis of cardiac conditions. The user is not intended to interpret or take clinical action based on the app output without consultation of a qualified healthcare professional.

The waveform generated by the ECG app is meant to supplement rhythm classification for the purposes of discriminating AFib from normal sinus rhythm and not intended to replace traditional methods of diagnosis or treatment.

CAUTION: Apple does not guarantee that you are not experiencing an arrhythmia or other health conditions when the ECG app labels an ECG as Sinus Rhythm. You should notify your physician if you detect possible changes in your health.

SECURITY: Apple recommends that you add a passcode (personal identification number [PIN]), Face ID or Touch ID (fingerprint) to your iPhone and a passcode (personal identification number [PIN]) to your Apple Watch to add a layer of security. It is important to secure the iPhone since you will be storing personal health information.

EQUIPMENT SYMBOLS

Manufacturer

Read instructions before use