



September 25, 2019

Via Courier

Jeffrey Shuren, M.D., J.D., Director
William Maisel, M.D., Director of Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue WO66-3521
Silver Spring, MD 20993-0002

Re: 1-800-CONTACTS: Marketing of Unapproved and Uncleared Ophthalmic Device

Dear Dr. Shuren and Dr. Maisel:

The American Optometric Association (AOA) respectfully requests the Office of Product Evaluation and Quality (OPEQ) review a medical device marketed by 1-800-CONTACTS, Inc. (1-800-CONTACTS). The device is currently referred to as “ExpressExam,” <https://www.1800contacts.com/express-exam/landing>, but was formerly known as “Online Prescriptions,” <https://youtu.be/U2F4A6AeUbU>. It is marketed directly to consumers as an online vision test that can be used to renew a contact lens prescription—without any examination of the patient and without any fitting of the contact lens by a qualified eye doctor.

There is no apparent evidence the device has been the subject of pre-market clearance or approval by the Food and Drug Administration. Presumably, the device is being distributed on the theory that it is substantially equivalent to visual acuity charts—and is currently being marketed as a class II device under § 510(k) of the FDCA (“the Act”), 21 U.S.C. § 360(k). But, as explained in this letter, the 1-800-CONTACTS device is not substantially equivalent to visual acuity charts. Therefore, the AOA respectfully submits that the device is being marketed in direct violation of the Act. It is both adulterated under 21 U.S.C. § 351(f)(1)(B) and misbranded under 21 U.S.C. § 352(o).

Indeed, the device is strikingly similar to the online eye exam of Opternative, Inc. (renamed Visibly in 2018), which was the subject of an FDA warning letter on October 30, 2017 (copy attached as Attachment A). In that letter, the agency stated that the On-Line Opternative Eye Examination Mobile Medical App was a device requiring premarket submission in order to allow the FDA to evaluate its safety and effectiveness. That warning letter further indicated that the device was both adulterated and misbranded, and it directed that Opternative immediately cease commercial distribution of the device. Significantly, the Opternative device was recently recalled for “lack of 510(k) clearance” in 2019.¹ For the reasons set forth below, AOA respectfully submits that the 1-800-CONTACTS device

¹ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=174633>

likewise lacks the appropriate FDA clearance or approval. Moreover, the device poses undue health risks to consumers.

I. 1-800-CONTACTS'S ONLINE EXAM

A consumer accesses ExpressExam online via a personal digital device, such as a smart phone, tablet, or computer. The first of four steps in the ExpressExam process advises the user to find a well-lit area and to wear his or her contact lenses before beginning the exam. The user also selects the prescription that he or she is seeking to renew. In the second step, the user indicates his or her age, the approximate date of the user's last comprehensive eye exam, and information about the user's eye health history.

The third step purports to photograph the surface of the user's eyes in order to evaluate redness and eye irritation. In that step, the user is instructed to hold the screen about a foot from his or her face. The fourth step purports to measure visual acuity. The user is instructed to stand the device upright (or have a friend hold it) and back away 10 feet. The user is then shown a series of block letters to read aloud, and the device records his or her responses. At the conclusion of the third and fourth steps, the user is asked whether he or she complied with applicable instructions. See Attachment B. According to 1-800-CONTACTS, a doctor then reviews the user's completed test results and issues a prescription within 24 hours, "all without going to the doctor's office."²

Even though 1-800-CONTACTS states that ExpressExam "...is not a comprehensive eye health exam,"³ it is marketed as a replacement for an examination by an eye doctor. In a Facebook post from August 30, 2018, for example, 1-800-CONTACTS claims, "Our Express Exam can be used right from your own home, meaning you won't need to spend time or money on annual ophthalmologist appointments." See Attachment C.

The ExpressExam website currently proclaims, "Renew your prescription online. At home, in your sweats, without talking to anybody. It's simple – no appointment necessary." The device description is: "Look at an eye chart and answer some questions – just like the doctor's office." These claims run directly counter to the FDA's safety recommendation⁴ that contact lens wearers obtain regular eye exams from an eye care professional. Moreover, the ExpressExam is, of course, not "just like the doctor's office" in that there is no one making sure that the test is performed correctly, no one checking the fit of the contacts lenses that are prescribed, and no eye doctor checking for ocular or other disease.

² <https://youtu.be/LMOGHaYM4gc>

³ See "Step 1" in Attachment B.

⁴ <https://www.fda.gov/medical-devices/contact-lenses/everyday-eye-care>

II. THE 1-800-CONTACTS DEVICE IS NOT SUBSTANTIALLY EQUIVALENT TO VISUAL ACUITY CHARTS

1-800-CONTACTS has registered with FDA as a manufacturer of a visual acuity chart (21 C.F.R. § 886.1150) and a medical device data system (21 C.F.R. § 880.6310). See Attachment D. We presume, therefore, that 1-800-CONTACTS is marketing the device on the theory that it is substantially equivalent to a visual acuity chart. However, like Opternative’s online eye exam, the 1-800-CONTACTS device is not substantially equivalent to a visual acuity chart.

As the four steps in the exam as described above make clear, the device does far more than measure visual acuity. It purports to provide a renewal prescription for contact lenses but without a direct evaluation of the fit or performance of the contact lenses on the user’s eyes.

Otherwise stated, the intended use of the 1-800-CONTACTS device is different from the intended use of a visual acuity chart. See, e.g., 21 C.F.R. § 886.9(a) (excluding from the scope of the 510(k) exemption for visual acuity charts any device “intended for a use different from the intended use of a legally marketed device in that generic type of device”). Specifically, the intended use of a visual acuity chart when used in the process of generating a contact lens prescription is for an eye care professional to measure a patient’s visual ability as one part of a comprehensive eye examination by an eye doctor designed to determine the patient’s ophthalmic health – including identifying the underlying defects that cause refractive errors, and the type and degree of correction needed. The intended use of the 1-800-CONTACTS device is to generate a renewed prescription for contact lenses with only post-test doctor review.

The 1-800-CONTACTS device is intended for use by a consumer without the immediate or direct involvement of an eye care professional, but visual acuity charts are intended to be used by eye care professionals with patient engagement to measure their patients’ visual acuity. On this issue, 21 C.F.R. § 886.9(a) is squarely on point in declaring that a “device is intended for a use different from the intended use of a legally marketed device in that generic type of device” if, among other things, “the device is intended for lay use where the former intended use was by health care professionals only.” The 1-800-CONTACTS device relies on the lay consumer’s self-reported adherence to its instructions in lieu of an eye care professional’s administration of the test, which is different from current uses of a visual acuity chart.

III. SAFETY AND EFFECTIVENESS ISSUES WITH THE DEVICE’S UNPROVEN TECHNOLOGY

Technology raising different issues of safety and effectiveness from legally marketed devices must be reviewed by CDRH in the context of a PMA or de novo request for classification before being marketed. See 21 U.S.C. § 360c(f)(1)(A), (i)(1)(A). As with Opternative’s device, 1-800-CONTACTS online exam raises significant safety and effectiveness issues. These include:

- A. The risk of inaccurate prescriptions that could harm consumers resulting from the self-administered nature of the exam and the technology it uses. Regardless of the baseline accuracy of the device’s exams—which is unknown—ambient light, glare, ambiguity in testing

distances from the device, and the condition of the consumer's camera and screen could all affect the accuracy of the tests. So, too, could the consumer's compliance with instructions and directions regarding how to set-up the device and follow the prompts.

- B. Potential for misdiagnosis of serious eye conditions that affect vision. The device—unlike a clinician performing an in-person comprehensive eye exam—is not able to diagnose underlying conditions or diseases such as glaucoma, cataracts, macular degeneration, or diabetes. Moreover, the device is unable to detect issues with the wear or care of a consumer's contact lenses so as to diagnose or even prevent potential complications. A refraction is part of the health assessment of the eye, in that one of the most effective and important indicators of ocular pathology is a reduction in best corrected visual acuity. One cannot meet the widely-accepted standard of care for eye examinations while separating the eye health assessment from the refractive analysis.
- C. Misfitted contact lenses. Contacts must be fitted to a particular diameter, base curves, edge design and lens material based not only on the consumer's refractive error, but also on the consumer's lifestyle as well as the oxygen demands of the cornea, to ensure that the lenses properly fit the eye. Improperly-fitted contacts put consumers at risk for a range of complications, from dry eye to a process called neovascularization. With neovascularization, fragile new blood vessels grow into the cornea and can leak and cause corneal disease that is undetectable by the individual wearing the contact lenses. The fitting process also gives an eye care professional the chance to check the consumer's eyes for complications -- and to talk to the consumer to assess the effectiveness of the lens and catch possible errors in prescriptions. How well the contact lens fit can also change over time. Therefore, one of the purposes of periodic re-examination of a contact lens patient is to ensure that the contact lens fit is still correct. That re-examination simply does not occur in the 1-800-CONTACTS program.

To be sure, there is a difference between the 1-800-CONTACTS device and the Opternative device. Specifically, the Opternative device generated prescriptions in the first instance, while the 1-800-CONTACTS device is marketed as a way to renew prescriptions. However, this difference does not point to a different result.

An individual's prescription needs may well change in the period between the initial prescription and the time for renewal for a variety of reasons such as advancement of a cataract or changes in the structure of the individual's eye. Moreover, during that time, the individual may have developed other one or more serious sight-threatening eye diseases which may need immediate intervention. Similarly, the individual may have developed a systemic disease that has potential ophthalmic manifestations such as diabetes or hypertension, or other diseases that can affect not only their refractive error, but also their ocular health. But by using the 1-800-CONTACTS device, the individual loses the ability to be checked for any of these conditions.

An additional problem with the 1-800-CONTACTS device is that, while consumers receive a prescription for the contact lens which they previously wore, they also receive a prescription for 1-800-CONTACTS' own

brand of AquaSoft contact lenses. Presumably, 1-800-CONTACTS relies on the fact that many consumers will choose its brand of lenses. Otherwise, they would not be offering a free eye exam using the device in question.

Notably, use of the 1-800-CONTACTS device to renew a prescription does not include a check for proper fit. In this connection, I would note that, in the AOA's evaluation of the 1-800-CONTACTS device, we found that the power listed on each prescription was the same, but the base curve varied. See Attachment E. This fact raises potentially serious issues because the AquaSoft contact lenses may not fit properly and are likely not to be checked for fit by an eye doctor.

On this issue, the agency's guidance⁵ to patients on "Buying Contact Lenses" is very relevant:

Beware of attempts to substitute a different brand than you presently have. While this may be acceptable in some situations, there are differences in the water content and shape between different brands. The correct choice of which lens is right for you should be based only on an examination by your eye care professional, not over the phone.

The 1-800-CONTACTS device is in direct conflict with this advice.

IV. REQUESTED ACTION

FDA should not permit the continued marketing of the 1-800-CONTACTS device until CDRH has reviewed the safety and efficacy issues raised by the device. Because the device is not substantially equivalent to visual acuity charts or any other existing classification regulation for ophthalmic devices, it is necessarily considered a Class III device for which an approved PMA is required. 21 U.S.C. §§ 360c(f)(1), 360e(a)(2). Marketing of the product is, therefore, unlawful until FDA has approved a PMA or has otherwise allowed the marketing of the device.

As with Opternative, we respectfully submit that the considerations set forth in this letter should lead to a prompt recall of the 1-800-CONTACTS device. We greatly appreciate your attention to this matter. If additional information is needed, please contact Kara Webb at kcwebb@aoa.org.

Sincerely,



Barbara L. Horn, O.D.
President, American Optometric Association

⁵ <https://www.fda.gov/medical-devices/contact-lenses/buying-contact-lenses>

Opternative Inc 10/30/17



10903 New Hampshire Avenue
Silver Spring, MD 20993

WARNING LETTER

October 30, 2017

Aaron Dallek, CEO
Opternative, Inc.
175 N. Ada Street
Chicago, IL 60607

Re: On-Line Opternative Eye Examination Mobile Medical App Device
Refer to CMS# 532477

Dear Mr. Dallek:

The United States Food and Drug Administration (FDA) has learned that your firm is marketing the On-Line Opternative Eye Examination Mobile Medical App device in the United States without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Under section 201(h) of the Act, 21 U.S.C. § 321(h), this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

FDA has reviewed your website and determined that the On-Line Opternative Eye Examination Mobile Medical App device is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The On-Line Opternative Eye Examination Mobile Medical App Device is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency, 21 C.F.R. 807.81(b).

On June 15, 2016, during a meeting held at our Agency, your firm was notified by the Office of Compliance and the Office of Device Evaluation that the On-Line Opternative Eye Examination Mobile Medical App device requires a premarket submission in order to allow the Agency to evaluate its safety and effectiveness.

The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at <http://www.fda.gov/> (<http://www.fda.gov/>)

[MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm).

([/MedicalDevices/default.htm](http://www.fda.gov/MedicalDevices/default.htm)) The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b). The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/d>

(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm>)efault.htm.

(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm>) The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Our office requests that Opternative, Inc. immediately cease activities that result in the misbranding or adulteration of the On-Line Opternative Eye Examination Mobile Medical App device, such as the commercial distribution of the device through your online website.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Field Inspections Support Branch
White Oak Building 66, Rm 3540
10903 New Hampshire Ave.
Silver Spring, MD 20993

Refer to the identification number CMS# 532477 when replying. We remind you that only written communication is considered as official. If you have any questions about the contents of this letter, please contact: Shanika Booth at 301-796-5771.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm. It is your firm's responsibility to ensure compliance with the applicable laws and regulations administered by FDA.

Sincerely,

/S/

CAPT Sean M. Boyd, MPH, USPHS

Deputy Director for Regulatory Affairs

Office of Compliance

Center for Devices and Radiological Health


More in 2017

[./ICECI/EnforcementActions/WarningLetters/2017/default.htm](https://www.fda.gov/iceci/enforcementactions/warningletters/2017/default.htm)




Attachment B

8:04

Step 1 of 4



Before you begin the exam...

-  ExpressExam is only available in select states, so we'll need to verify your location
-  Find a quiet, well-lit area with 10 feet of space
-  Make sure you're wearing your contacts


☒ I understand that ExpressExam is a vision test which provides renewals of contact lens prescriptions where appropriate. It is not a comprehensive eye health exam.

Continue

8:05


Choose Rx

Select Rx for renewal:




	POWER	BC	DIA
R	-9.50	8.4	14.00
L	-9.50	8.4	14.00

Expires Oct 3, 2019



	POWER	BC	DIA
R	-9.50	8.8	14.10
L	-9.50	8.8	14.10

Expires Aug 21, 2020






	POWER	BC	DIA
R	-9.50	8.4	14.00
L	-9.50	8.4	14.00


Expires Aug 21, 2020

or

Add another Rx

8:05   

< Step 2 of 4



Patient information

Let's confirm that ExpressExam will work well for you

How old are you?

Age
38




Approximate date of your last comprehensive eye health exam.

Last exam
Under 1 yr ago


What is your gender (optional):

Gender
Female

Continue

8:05   

< Step 2 of 4



Eye health history

Check all that apply

Have you:

☐ Had an eye infection or eye surgery since your last in-person eye exam

☐ Used prescription eye drops since your last in-person eye exam

Are you currently experiencing:

☐ Pain, redness, irritation, or itchiness

☐ Blurred or double vision while wearing contacts

☐ High sensitivity to brightness

☐ Any new bright flashes or floaters

☐ Temporary loss of vision

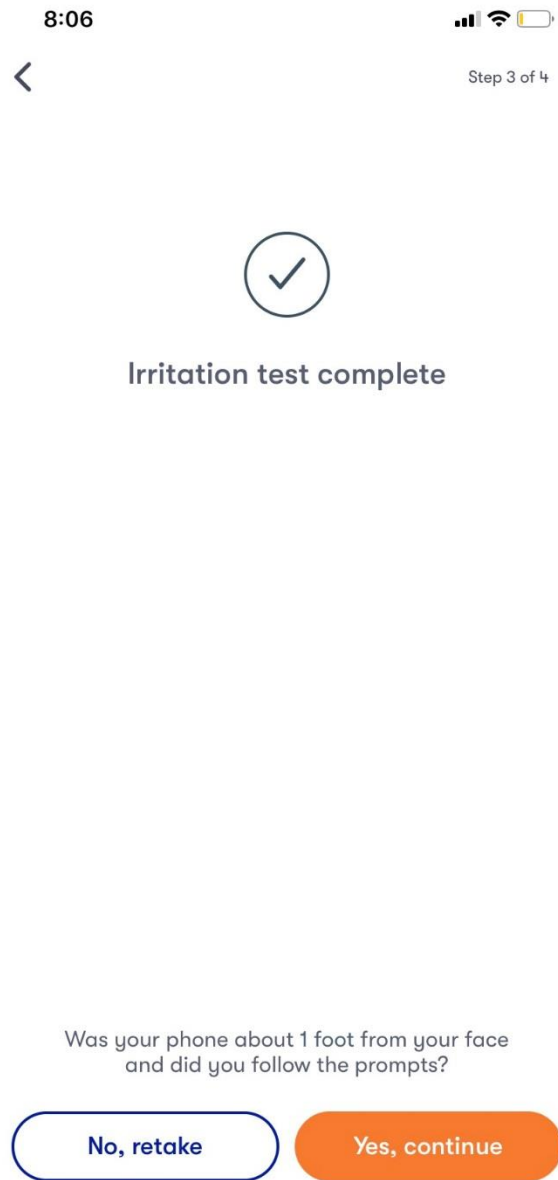
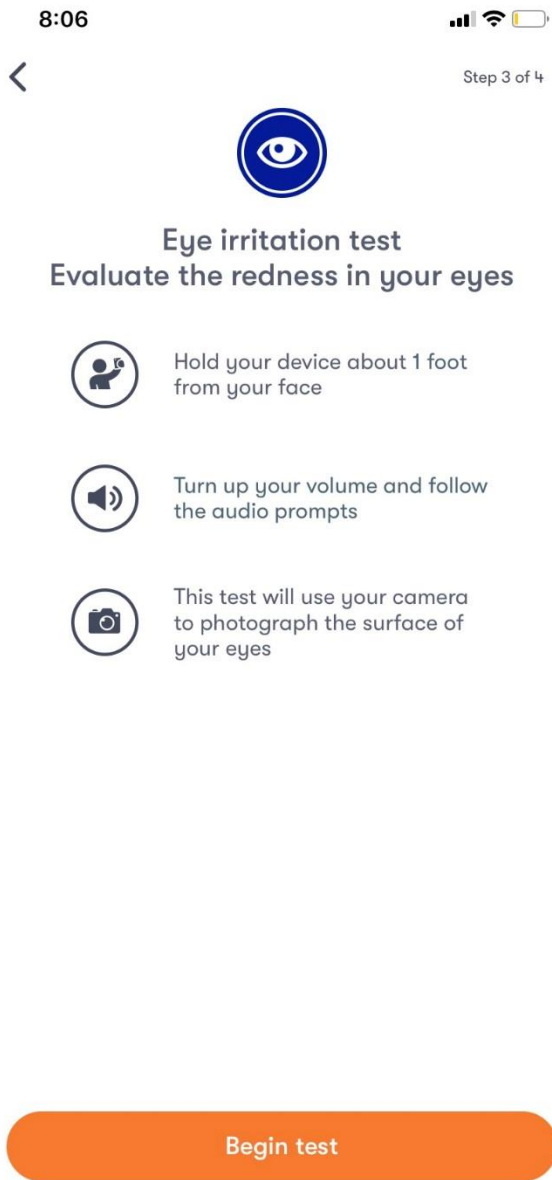
☐ Moderate to severe dry eye

☐ Discomfort or other issues while wearing contacts

Have you ever been diagnosed with:

☐ Corneal disease such as keratoconus, dystrophy

Continue





Visual acuity test
To ensure you see clearly
in your current contacts



Stand your device upright (or have a friend hold it) with the screen facing you



While facing the screen, back up until you are 10 feet away



This test will use your microphone to record your responses

Begin test



U R L D





Visual acuity test complete

N K O L
I

Did you successfully read the eye charts aloud while covering the appropriate eye?

Did you remain 10 feet from your screen?

No, retake

Yes, continue

Attachment C



EXPRESS
exam

free

Renew your prescription online.

At home, in your sweats,
without talking to anybody.

Start your exam

It's simple – no appointment necessary.



Take the exam

Look at an eye chart and answer some questions – just like the doctor's office.




Get your new Rx

A doctor reviews your exam results and issues your new prescription within 24 hours.

Attachment D

U.S. Department of Health & Human Services


U.S. FOOD & DRUG
 ADMINISTRATION




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1 to 10 of 100 Results for State in which Establishment is located : UT*

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Establishment Name		Registration Number	Current Registration Yr
1800 CONTACTS, INC	UT/USA	3011080538	2019
<ul style="list-style-type: none"> Lenses, Soft Contact, Daily Wear - One Day Flat Pack (Bioxifilcon A) Daily Disposable Soft Contact Lens 			Repackager/Relabeler
<ul style="list-style-type: none"> Chart, Visual Acuity - 1800 CONTACTS, INC. 			Manufacturer
<ul style="list-style-type: none"> Medical Device Data System - 1800 CONTACTS, INC. 			Manufacturer
A Cute Baby, Inc.	UT/USA	3009243271	2019
<ul style="list-style-type: none"> Pump, Breast, Powered - A Cute Baby, Drive: Medquip, Rumble Tuff, Viverity 			Complaint File Establishment
<ul style="list-style-type: none"> Pump, Breast, Non-Powered - Medquip, Rumble Tuff, Viverity 			Complaint File Establishment
ABL Manufacturing, LLC	UT/USA	3008396914	2019
<ul style="list-style-type: none"> Dressing, Wound, Drug - Dermasyn/AG Wound Dressing Gel; Silver SG Wound Dressing Gel; SILVRSTAT® Antibacterial Wound Dressing Gel 			Contract Manufacturer
<ul style="list-style-type: none"> Dressing, Wound, Drug - Armor Gel Wound Dressing Gel; ASAP OTC Wound Dressing Gel; Q Restore Wound Dressing Gel; Rescue Wound Dressing Gel 			Contract Manufacturer
<ul style="list-style-type: none"> Dressing, Wound, Drug - CareSTAT Wound Dressing Gel 			Contract Manufacturer
ABL Medical, LLC	UT/USA	3007536356	2019

Attachment E

1-800-CONTACTS provides patients with their own brand of contact lenses, even if patients have not been fitted with these lenses. Note difference in base curve ("BC") below.

https://www.1800contacts.com/n


LAST ORDERED

RX EXPIRES

Rx Details

R


POWER	BC	DIA
-9.50	8.5	14.1

 **✓ Rx on File**
When we have your Rx image on file, we are able to process your shipments faster.
[Download](#)

DOCTOR

ExpressExam

DELETE RX

☐ 

RIGHT EYE
AquaSoft™ Daily 15pk


LAST ORDERED
07/17/2019

RX EXPIRES
07/17/2020

Rx Details

R

POWER	BC	DIA
-9.50	8.8	14.1

 **✓ Rx on File**
When we have your Rx image on file, we are able to process your shipments faster.