1. Caution

READ ALL INSTRUCTIONS AND WARNINGS CAREFULLY BEFORE USE.

2. Description

BeCare Neuro Link mobile application allows the user to perform a series of directed activities to assess general neurological function and see how they compare with the general public. The mobile application provides a platform for users to perform activities in the comfort of their own home as often as desired. Users can review the results of these activities themselves or they can share the results with their treating clinician.

3. Intended Use

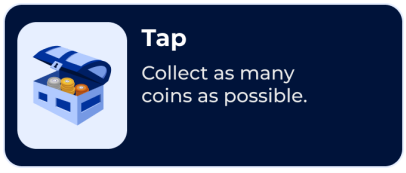
BeCare Neuro Link is a mobile application platform providing the user with a series of self-administered mobile app activities designed to demonstrate general neurological function.

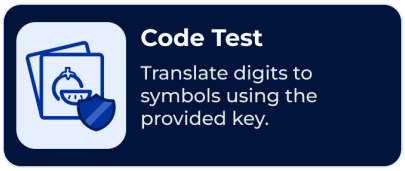
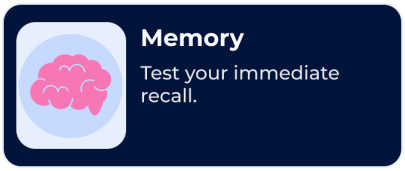
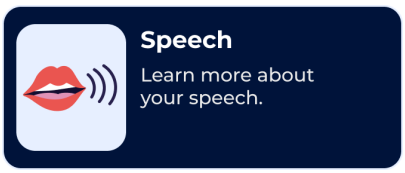
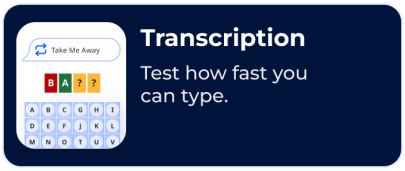
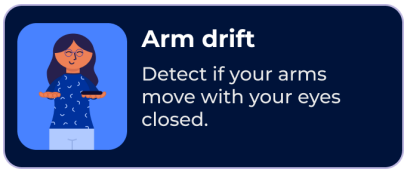
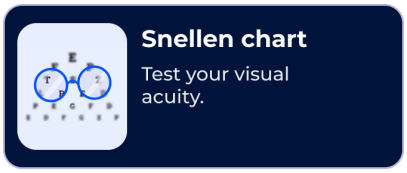
4. Warnings

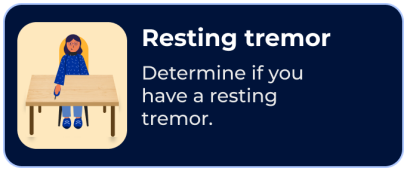
When performing any exercises involving walking, be aware of your surroundings to avoid falling or bumping into any nearby objects.

5. Instructions for Use

The BeCare Neuro Link mobile application includes a suite of activities that the user can perform, and each activity includes a guided tutorial available from the activity screen. The activities include:

	This activity measures how long it takes you to walk 25 feet. ***WARNING: Be sure to look at your surroundings, not at your phone, when walking!***
	You hold your device flat against your palm (not vertically). You start with your phone in the right hand and with your arm down. You then raise your arm with the cell phone up and down until you hear the end-of-game sound. You will then put the phone in the palm of your left hand and repeat the activity.
	This activity starts with instruction to collect various coins that appear at different places on the screen by tapping on the coin's location as quickly as possible. Each time you tap the screen, the app records the time of the tap and the location of the tap vs the location of the coin.
	You are instructed to move an object on the screen along a curvy path as quickly and as closely as possible using your index finger. The app measures deviations outside the path as well as circumstances in which these deviations occur. You are asked to repeat the test 3 times on each side, starting with the right index finger, and results are

	presented as the time it takes you to move the object from point to point along the path.
	The Timed Up and Go (TUG) activity starts with instruction and a set of icons corresponding to the 6 stages of transitions: sitting, standing, walking, turn back, walk back, and sit back. You hold the mobile device in your hand so the screen is visible. When you press “Start”, a timer starts that continues until the activity ends. The phone detects your transition between each separate stage of the test. As each stage is detected, its time is recorded by the app, and the icon corresponding to the stage changes from the background color to green. ***WARNING: Be sure to look at your surroundings, not at your phone, when walking!***
	You are asked to decode a message using decoding key. A series of symbols are paired with letters or words to be used as the key. The coded message is provided in symbols. You start the test by pressing a “Begin" button, and the test stops when you complete the decoded message.
	For this activity, you are presented two animals and asked to memorize them. After several seconds, one of the animals will disappear, and you will be shown a number of different animals and asked to choose the image that just disappeared. If you cannot remember correctly, the game will reset.
	You will see a series of 10 words written in colored letters. Tap on the ribbon that matches the color you see on the word. Do not tap the color you read. Please use the index finger of your dominant hand to complete this task.
	This activity uses the device oscillator to produce different patterns distinguishable to you as vibrations. The app records whether you detect the change. You will hold the phone in one hand to sense the vibration and use your index finger other on the other hand to press the button ”Vibration Change” when you detect a change.
	You will be asked to repeat different words and sounds. The results of this activity will produce measures of how fast you speak and the clarity of your speech.
	In this activity, you will see and hear a short phrase, and then you must type that phrase using a special keyboard that changes every time a new phrase is heard. The app records the time to complete typing the phrase as well as the time interval and time variance between keystrokes. Please use the index finger of your dominant hand to complete this activity.
	You will be asked to stand with your armed stretched out straight ahead of you palms up., resting your phone on your right palm. You will need to close your eyes and maintain that position without moving your arms for 20 seconds. A voice will tell you to put your arms down. The same activity will be performed with the left arm.
	This activity determines your visual acuity. It replicates the eye chart used in your eye doctor's office when she asks what letters you see.

	You will need a pen and to sit at a table with your right arm outstretched comfortably with your elbow resting on the table. You will place the pen under the screen of the phone lengthwise and then rest your hand lightly on the phone without gripping it. This position will be maintained for 25 seconds and then repeated with the left hand.

About Me
In addition to the activities described above, the BeCare Neuro Link mobile application includes an "About Me" section where you can keep track of how you are feeling and complete helpful questionnaires (such as Health History, Quality of Life, Happiness, and Patient Health Questionnaire-9).

Customizing My App
You can customize your BeCare Neuro Link mobile application through the "More" page, where you have options to choose what language you want to view the app in, your own avatar, choose how fast you want to hear the voice over, and choose between the dark and light options.

Sharing My Results
You can share your results with your clinician using the "Healthcare Provider" option located on the "More" page. You will first need to register your Healthcare Provider, then request to share your data with them. From here, you can also see the status of your requests.

6. Disclaimer

BeCare Neuro Link is intended for educational and informational purposes only. BeCare Neuro Link does not and cannot diagnose any health condition, provide a medical opinion, and/or substitute for professional medical advice. It is the user's responsibility to consult with a doctor or other appropriately licensed professional if you have any questions or concerns about potential medical conditions as a result of the information you receive from using this product.

7. Manufactured By

BeCare Link
8 North Ward Avenue
Rumson, NJ 07760
www.becarelink.com

7. References

The Neuro Assessments fall into 3 groups. Links to sources for medical info are listed for each group.

Group 1

1. Memory
2. Tap
3. 25 Ft Walk
4. Arm Elevation
5. Path
6. TUG: Up and Go
7. Code
8. Stroop
9. Transcription
10. Vibration

Group 2

11. Speech

Group3

12. Snellen
13. Resting Tremor
14. Finger to Nose
15. Eye Movements

All Neuro Assessments in Group 1 have been previously identified as neuro assessments in the applicant's prior application to the FDA for approval of a" Machine Learning method for calculating the Expanded Disability Status Scale (EDSS), Calculate And Report Clinical Scores Corresponding To The Multiple Sclerosis Functional Composite (MSFC), and Vibration Detection Sensory Activity Functions".
Group 1 assessments are specifically addressed in these paragraphs from November 29, 2021 FDA response letter with the complete response from the FDA appearing on the following page, after which Group 2 and Group 3 sources are identified. It is important to note that the assessments were reviewed by the FDA and the assessments were not subject to additional regulation even though the machine learning application is subject to regulation.

Tap Task: Fine Motor Function/Rapid Finger Movement Test, Path Test: Upper Extremity Coordination Test, Transcription Test: Auditory-Comprehension-Typing Test (ACT) Test, Contrast Sensitivity Test, and Animals in a Box Memory Activity: These five functions meet the definition of a device under section 201(h) of the FD&C Act. However, these functions represent functions that are exempt from premarket notification requirements, as described in 21 CFR 882.1470 Computerized Cognitive Assessment Aid (product code PTY). Therefore, in accordance with the "Multiple Function Device Products: Policy and Considerations" guidance, these functions are considered "other functions" as part of the BeCare MS Link multiple function device product.
Timed Up and Go (TUG) Test, Timed 25-step Walk, Six Minute Walk, Coded Message Cognitive Test, and Arm Swing Test Functions: These five functions represent functions that are not the focus of FDA's oversight, as described in the "Policy for Device Software Functions and Mobile Medical Applications" guidance (https://www.fda.gov/media/80958/download). Therefore, in accordance with the "Multiple Function Device Products: Policy and Considerations" guidance, these functions are considered "other functions" as part of the BeCare MS Link multiple function device product.

November 29, 2021

BeCare Link, LLC
8 Ward Ave
Rumson, NJ 07760

Re: C200148
Product Name: BeCare MS Link Mobile Application ("BeCare MS Link")
Dated: December 1, 2020
Received: December 2, 2020

Dear Wade Munsch:

We have reviewed the above referenced request for information, submitted in accordance with Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), regarding the regulatory requirements applicable to the BeCare MS Link Mobile Application ("BeCare MS Link"). Based on the information provided in your submission, we believe the BeCare MS Link is a "multiple function device product", providing at least

one “device function” requiring premarket authorization (i.e., “device function-under-review”) and at least one “other function”, as these terms are defined in the guidance document entitled “Multiple Function Device Products: Policy and Considerations” (https://www.fda.gov/media/112671/download). Please note, in accordance with the guidance document cited above, FDA may assess the impact of “other functions” when assessing the safety and effectiveness of the “device functions-under-review” of a multiple function device product. Therefore, below we delineated the device regulatory considerations of the distinct functions and have provided the regulatory pathway for the BeCare MS Link:

Tap Task: Fine Motor Function/Rapid Finger Movement Test, Path Test: Upper Extremity Coordination Test, Transcription Test: Auditory-Comprehension-Typing Test (ACT) Test, Contrast Sensitivity Test, and Animals in a Box Memory Activity: These five functions meet the definition of a device under section 201(h) of the FD&C Act. However, these functions represent functions that are exempt from premarket notification requirements, as described in 21 CFR 882.1470 Computerized Cognitive Assessment Aid (product code PTY). Therefore, in accordance with the “Multiple Function Device Products: Policy and Considerations” guidance, these functions are considered “other functions” as part of the BeCare MS Link multiple function device product.

Timed Up and Go (TUG) Test, Timed 25-step Walk, Six Minute Walk, Coded Message Cognitive Test, and Arm Swing Test Functions: These five functions represent functions that are not the focus of FDA’s oversight, as described in the “Policy for Device Software Functions and Mobile Medical Applications” guidance (https://www.fda.gov/media/80958/download). Therefore, in accordance with the “Multiple Function Device Products: Policy and Considerations” guidance, these functions are considered “other functions” as part of the BeCare MS Link multiple function device product.

Based on the information provided in your submission, BeCare MS Link do not conform to the requirements of current existing regulations. Therefore, we believe that BeCare MS Link is appropriate for classification through the De Novo pathway for reasons explained below.

As previously stated, we believe that the BeCare MS Link may be suitable for classification under section 513(f)(2) of the Act, also referred to as De Novo classification or Evaluation of Automatic Class III Designation. This section of the Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA), 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. 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).

However, FDA is aware of devices that use an individual’s score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. These Computerized Cognitive Assessment Aids are Class II type devices, exempt from the premarket notification [510(k)] requirements of the Act, subject to the general limitations to the exemption found in 21 CFR 882.9 and the specific limitations that the device is not intended for diagnostic assessment of specific diseases or conditions and relies on inputs from visual cues, auditory cues, and/or functional use of the hand. Because the described vibration detection sensory

activity function introduces reliance on patient responses to mechanical stimuli as a device input, we believe that this function exceeds the limitations to the exemption in 21 CFR [886.9(b)]. Therefore, removing references to providing surrogate measures for clinical scoring systems for disability measurement in MS from your device's indications and associated design may allow you to utilize the 510(k) pathway if an appropriate predicate is identified. If you pursue these modifications, we recommend that you further engage with CDRH to discuss the performance data needed to support a future 510(k) submission.

Additionally, we believe that you will need to provide clinical performance data to support either a 510(k) submission (if you choose to pursue the optional pathway as described in the previous paragraph) or a De Novo submission for this device. We strongly recommend that you contact Jay Gupta, Assistant Director, THT5A3, at 301-796-2795, to discuss developing an appropriate clinical trial protocol and strongly suggest that you consider submission of a Pre-Submission to seek additional constructive feedback. Please refer to FDA's guidance document entitled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" available at the following weblink: https://www.fda.gov/media/114034/download.

Section 513(g) of the Act requires the agency to provide information about the regulatory requirements applicable to a particular type of device. The response represents FDA's best judgment about how the product would be regulated, based upon our review of the information you have provided, including your description of the product and its intended use. FDA's response to a 513(g) request is not a classification decision for a device and does not constitute FDA clearance or approval for commercial distribution.

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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 regarding this letter, please contact Jay Gupta, Assistant Director, THT5A3, at 301-796-2795.

Sincerely,

Sergio M. DeCastillo

-S

for Christopher Loftus, M.D.
Acting Director

Digitally signed by Sergio M. De Del Castillo -S
Date: 2021.11.29 14:46:16 -05'00'

OHT5: Office of
Neurological and
Physical Medicine
Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological
Health

The Group 2 Speech metrics are:
Articulation rate:

Slowed articulation rate is a sensitive diagnostic marker for identifying non-fluent primary progressive aphasia
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5531197/

Cepstral Peak Prominence (dysphonia):

Cepstral peak prominence (CPP) is an acoustic measure of voice quality that has been qualified as the most promising and perhaps robust acoustic measure of dysphonia severity
https://www.sciencedirect.com/science/article/abs/pii/S1746809414000986
https://journals.sagepub.com/doi/abs/10.1177/00034894031120040 6?journalCode=aora
Spasmodic Disphonia can be an initial presentation of ALS.
https://www.sciencedirect.com/science/article/abs/pii/S0892199796800282

Group3: These are standard neurologic tests performed routinely by all neurologists.

1. Snellen-The Snellen test is employed by ophthalmologists and neurologists in the form of a chart of letters of diminishing size to determine visual acuity. Normal vision is set at 20/20, with the numerator representing the distance that the patient is standing from the chart (in feet) and the denominator representing the distance from which a person with perfect eyesight is still able to read the smallest line that the patient can clearly visualize. https://pubmed.ncbi.nlm.nih.gov/32644387 The app presents letters in size that correlate proportionately to the traditional Snellen chart.

2. Resting Tremor- Neurologists will observe for involuntary, rhythmic and oscillatory hand movements while the hands are at rest in a patient's lap or on a stationary surface. The most common cause is Parkinson's Disease and the tremor is generally at a rate of 5-7 Hz. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7707047/ The NeuroLink App measures these oscillating movements, measuring the amplitude and frequency in Hz.

3. Finger to Nose- Neurologists ask patients to take their finger and touch the doctor's finger (which s/he will move each time) and then touch their nose several times. This task measures cerebellar function, in particular the presence of dysmetria. Studies have concluded that the finger to nose test is valid, reflecting temporal and spatial coordination . https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5259887/ The Finger to Nose test mimics the test as performed in clinical evaluations in the doctors' offices.

4. Eye Movements- Neurologists will ask patients to follow their finger with their eyes, evoking upgaze, downgaze and lateral gaze. This assesses function of cranial nerve III, IV and VI. In a normal patient, both eyes will move symmetrically in parallel. Any deviation suggests the aforementioned cranial nerve dysfunction. Further a "bouncing" of the eyes on lateral or vertical gaze, called nystagmus, suggests brainstem and/or cerebellar dysfunction. https://pubmed.ncbi.nlm.nih.gov/35239052/