Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

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

PAYMENT IDENTIFICATION NUMBER: **MD**
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)
Hive Industries, 161 College Ave, Medford MA, 02155

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
N/A

2. CONTACT NAME Jake Hellman

2.1 E-MAIL ADDRESS jake.hellman@hive.com

2.2 TELEPHONE NUMBER (include Area code)
617-417-2521

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/oc/mdufma

Select an application type:
[X] 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)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[ ] 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)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA [ ] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: N/A

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 our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[X] 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

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION $ 2,614.00

Form FDA 3601 (01/2007)

510(k) Submission

Submitted: 5/7/2016 Group: 2

Jake Hellman (jake.hellman@tufts.edu), Rob Lasell (robert.lasell@tufts.edu), Katia Kravchenko (catherine.kravchenko@tufts.edu), Ferdinand Dowouo (ferdinand.dowouo@tufts.edu), Trish O'Connor (patricia.o_connor@tufts.edu), Aristana Scourtas (aristana.scourtas@tufts.edu)

MMDA FOOD AND DRUG ADMINISTRATION
Center for Devices and Radiological Health
161 College Avenue
Medford, MA 02155
RE: BeeBop™ Traditional 510(k) Notification

To whom it may concern:

We submit the following 510(k) Premarket Notification for Hive, Inc. of Medford, MA for FDA evaluation and approval of the therapeutic children's toy BeeBop™ under the requirements of 21 CFR 807. This device is a Class II device by 21 CFR 890.5360, labeled "Measuring exercise equipment" under Subpart F--Physical Medicine Therapeutic Devices. To the best of our knowledge this device matches the product code 89 I--SD as a measuring exerciser in physical medicine.

BeeBop™ may be commonly known as a therapeutic adaptive toy primarily for pediatric patients with neuromotor and neuro-ophthalmological dysfunction, most similar to the Switch Adapted Toy (see pg. 9). BeeBop™ stands alone as a finished component; major components not manufactured by these authors include the Arduino Uno and the Adafruit BLE nRF8001 Breakout. No applicable mandatory performance standards or special controls exist for this device.

BeeBop™ consists of a peripheral device that communicates via Bluetooth with an Apple iPhone application, also called BeeBop. The application would be available for free download from the iTunes Application Store immediately upon purchase of the BeeBop peripheral device. The peripheral is a series of 4 "drum-like" buttons, each approximately 6 inches in diameter and 4 inches high, that light up in synch with music played from the BeeBop app. The patient is expected to hit the appropriately-lit button in accordance with the music; correct and incorrect hits are logged by the app, along with the forcefulness and reaction time of the hit. The device serves to enhance pre-existing physical therapy exercises. The game may be customized via the app by an occupational therapist (OT) or other caregiver in the following ways: choice of song, tempo of song, number of active "drums", arrangement of drums on a horizontal or vertical plane, and difficulty of each song as measured by the number of drums to hit per a set interval of time. Data is recorded by the app for patient evaluation and follow-up treatment.

Any questions or requests for additional documentation should be directed to any of the authors listed above at their respective email addresses.

Thank you for your consideration,
Group 2

TABLE OF CONTENTS

STATEMENT OF INDICATIONS FOR USE

The intended users of BeeBop™ are those who suffer from neuromotor and neuro-ophthalmological dysfunction, including but not limited to users with cerebral palsy (CP), hemiplegia, and/or traumatic brain injuries (TBI) and their respective caregivers. In moderate to severe cases, these conditions can result in limited mental and physical capabilities, often altering the sufferer's daily activities, behaviors, and interpersonal interactions permanently. BeeBop™ is intended to be used in the settings in which an Occupational Therapist (OT) might operate, such as a hospital or private office. The device is intended to aid in the care that an OT can provide by serving as a therapeutic toy that engages and excites the user while simultaneously working the patient's coordination, cognitive processing, and arm extensibility at the OT's discretion. The device allows the OT to make quantifiable measurements of the subject's abilities and improvement or lack thereof. These measurements are presented in the form of graphs and tables.

510(K) SUMMARY

BeeBop™ is a pediatric toy meant to assist in measuring, and improve, the effects of traumatic brain injury. The trade name is BeeBop™. It is commonly known as a drumset, but it has a set of enhanced features that make it unique and useful.

BeeBop™ is very similar to the Switch Adapted Toy (http://www.rehabmart.com/product/interactive-drum-17071.html) which can be used to play more than six interactive tunes. The user presses switches to play the bass drum, snare drum, and cymbals along with the playing music. The Interactive Drum can be used to teach cause and effect and to provide auditory stimulation. BeeBop™ is similar because it uses switches which act as drums to control the flow of music. It can also be used to teach cause and effect and to provide auditory stimulation, as well as visual stimulation and mobility practice.

This therapy tool could be used in interventions for children and adults with motor disorders and motor impairments secondary to traumatic injuries or congenital conditions, including cerebral palsy, traumatic brain injury, and muscular dystrophy.

The tool provides customizable targets (in the form of drums) which assist in the rehabilitation of upper extremities by delivering sensory and sequential prompts. The targets contain sensors to determine the force with which the patient hits them along with lights and speakers in order to provide the patient with cues to hit the targets. The customizable aspects of the tool include the height, placement, and tilt of the targets, the force required to register a hit, the pace at which the cues occur, the types of cues used, and the number of targets in use. The therapist would be provided with data from the tool, such as response time and hit force (and other mechanical and electrical measurements).

BeeBop™ consists of a series of mechanical switches which are activated upon drum hits. There are also eight LEDs that surround each drum head (in four different colors) and a set of eight green LEDs that surround each drum head to indicate that the correct drum was struck. The drums also contain an accelerometer which can be used to collect force data when the drum is struck. All of this information is processed by an Arduino Uno which sends the data via bluetooth to an iPhone application where it is processed and presented to the user.

TRUTHFUL AND ACCURATE STATEMENT

We certify that, in our capacities at Hive Industries, a medical device developer, we believe to the best of our knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____	_____
[signature]	[signature]
_____	_____
[typed name]	[typed name]
_____	_____
[date]	[date]

_____	_____
[signature]	[signature]
_____	_____
[typed name]	[typed name]
_____	_____
[date]	[date]

_____	_____
[signature]	[signature]
_____	_____
[typed name]	[typed name]
_____	_____
[date]	[date]

PROPOSED LABELING

Indicated Use: BeeBop™ is intended for use as an aid to mental and physical stimulation for patients suffering from traumatic brain injury.

Contraindications: Those with a known adverse reaction to loud sounds or bright lights should not use BeeBop™.

SPECIFICATIONS

BeeBop™ consists of a set of targets in the form of buttons that are attached to electronic switches that are triggered when the buttons are hit and that are coordinated with music. An accelerometer and gyroscope are attached to each button, measuring the acceleration of the button at the time of each hit in order to determine the force of the hit. LEDs are also attached to each button in order to provide cues. All of these buttons are connected to a microprocessor that processes the information and cues which buttons are to be hit. A bluetooth link connects to a phone, where the BeeBop app is running, so that the music will play and so that the patient and therapist can control the settings and review the data. The settings allow the buttons and cues to be customizable. In addition, the buttons can be spread and tilted to adjust for the patient's reach and motor control needs.

Each target measures 6±1 inches in diameter and is 4±0.5 inches tall. The four drums are each represent one color (red, orange, yellow, and blue) because the drum surface is the specified color and there are 8 LEDs of the same color surrounding the target which serve as cues. In addition, each target is surrounded by 8 green LEDs which light up when the correct target is struck. Each drum head is attached to the target base via three springs with 1±0.5 inches of travel towards the target base and away when being struck. The targets can be affixed to a large mount via velcro and their placement and spacing is therefore variable. In addition, the orientation of the mount can be changed such that the drums can be horizontal, vertical, or anywhere in between. The device is run off of 5 volts via USB or via a battery source greater than 5 volts.

SUBSTANTIAL EQUIVALENCE COMPARISON

Device with Substantial Equivalence	**Intended Use**	**Reasons for Equivalence**
Fitbit	Fitness tracker	Bluetooth connection to phone app
Pulse Oximeter	Heart rate measurement	Use of light emitting diodes
AbleNet Simple Switch	Large button for easy access	Large buttons
Switch Adapted Toy	Teach cause and effect and to provide auditory stimulation through music	Buttons that control musical game
Colorful Game Buzzers	Large buzzers for use in any game	Large colorful buttons
Musical Snail Specially Adapted Toy	Help with note and color recognition, hand-eye coordination, and listening skills through music	Buttons which control music

BeeBop™ is similar to the Fitbit device (https://www.fitbit.com) because both devices use a bluetooth link to share data with an iPhone application.

BeeBop™ is similar to pulse oximeters because both devices use LEDs in close proximity to the human body. It is known that the LEDs in pulse oximeters cause no harm to the human body and so there is no reason why the LEDs used in BeeBop™ should.

BeeBop™ is similar to the AbleNet Simple Switch (https://www.ablenetinc.com/technology/switches) because both devices consist of a large button that is to be pressed by the user. In this present case the drum head.

BeeBop™ is similar to the Switch Adapted Toy (http://www.rehabmart.com/product/interactive-drum-17071.html) because the Swtich Adapted Toy is capable of playing more than six interactive tunes. The user uses the switches to play the bass drum, snare drum, and cymbals along with the playing music. Interactive Drum is intended to teach cause and effect and to provide auditory stimulation.

BeeBop™ is similar to the Colorful Game Buzzers (http://www.rehabmart.com/product/colorful-game-buzzers-35653.html) because the Colorful

Game Buzzers turn any lesson into a game; when pressed they emit fun sounds, like a horn, a boxing bell, a doorbell, or a "boing".

BeeBop™ is similar to the Musical Snail Specially Adapted Toy (http://www.rehabmart.com/product/musical-snail-specially-adapted-toy-32179.html) beacuse the Musical Snail Specially Adapted Toy is designed to help with note and color recognition. The user plays songs by hitting the differently-colored switches; each note is color coded in the included music. The Musical Snail Specially Adapted Toy also helps to increase eye-hand coordination and improve listening skills.

PERFORMANCE

No performance data is available at this time because the device is not yet completed. Testing will soon begin and performance data will be forwarded to MMDA_FDA as soon as it is ready.

ADDITIONAL INFORMATION

The BeeBop™ device connects to a phone(iphone) application via Bluetooth Low Energy at 2.4 GHz. BeeBop™ uses the nRF8001 bluetooth breakout board which complies with all FCC regulations.