
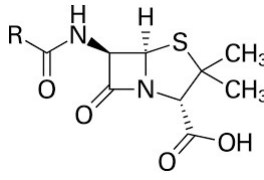


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# It's about 100 years ago

# But what if he lived in 2021?

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# What if this was designed in 2021?



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**Volume 122, Issue 2**  
August 2008



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ARTICLES | AUGUST 01 2008

## A Video Game Improves Behavioral Outcomes in Adolescents and Young Adults With Cancer: A Randomized Trial 🏆

Pamela M. Kato, PhD, EdM; Steve W. Cole, PhD; Andrew S. Bradlyn, PhD; Brad H. Pollock, PhD, MPH

Address correspondence to Pamela M. Kato, PhD, EdM, University Medical Center Utrecht, Center for Patient Safety, Housepost number Q 05.4.300, PO Box 85500, 3508 GA Utrecht, Netherlands. E-mail: [pkato@umcutrecht.nl](mailto:pkato@umcutrecht.nl)  
*Pediatrics* (2008) 122 (2): e305–e317.  
<https://doi.org/10.1542/peds.2007-3134>   [Article history](#) 🕒


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**OBJECTIVE.** Suboptimal adherence to self-administered medications is a common problem. The purpose of this study was to determine the effectiveness of a video-game intervention for improving adherence and other behavioral outcomes for adolescents and young adults with malignancies including acute leukemia, lymphoma, and soft-tissue sarcoma.




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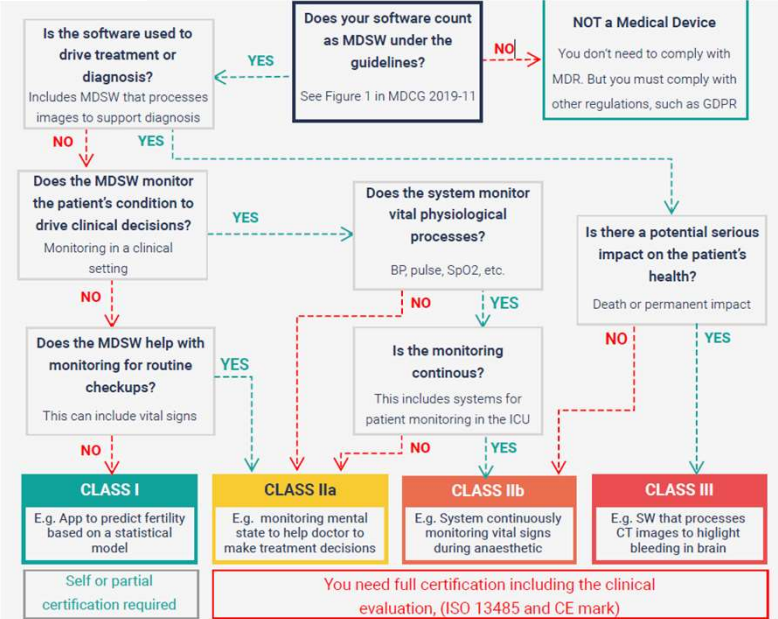
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Crucial is the intended use.


The purpose!



The flowchart determines the classification of software based on several criteria:

- Does your software count as MDSW under the guidelines?** (See Figure 1 in MDCG 2019-11)
  - NO:** NOT a Medical Device. You don't need to comply with MDR. But you must comply with other regulations, such as GDPR.
  - YES:** Proceed to the next question.
- Does the software used to drive treatment or diagnosis?** (Includes MDSW that processes images to support diagnosis)
  - NO:** CLASS I. E.g. App to predict fertility based on a statistical model. Self or partial certification required.
  - YES:** Proceed to the next question.
- Does the MDSW monitor the patient's condition to drive clinical decisions?** (Monitoring in a clinical setting)
  - NO:** CLASS I.
  - YES:** Proceed to the next question.
- Does the system monitor vital physiological processes?** (BP, pulse, SpO2, etc.)
  - NO:** CLASS I.
  - YES:** Proceed to the next question.
- Is the monitoring continuous?** (This includes systems for patient monitoring in the ICU)
  - NO:** CLASS I.
  - YES:** Proceed to the next question.
- Is there a potential serious impact on the patient's health?** (Death or permanent impact)
  - NO:** CLASS I.
  - YES:** CLASS III. E.g. SW that processes CT images to highlight bleeding in brain. You need full certification including the clinical evaluation, (ISO 13485 and CE mark).

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## What if not Class I ?

		Significance of the information		
		Treat or diagnose	Drive clinical management	Inform treatment
What is the risk of harm?	Critical	Class III	Class IIb	Class IIa
	Serious	Class IIb	Class IIa	Class IIa
	Other	Class IIa	Class IIa	Class IIa



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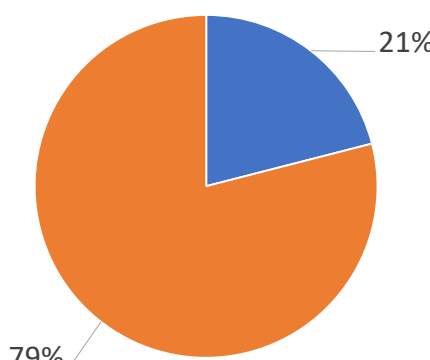
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Existing Apps n = 271





Category	Percentage
Medical Device	21%
NOT a Medical Device	79%

National Institute for Public Health and the Environment  
Ministry of Health, Welfare and Sport


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# What about new games, to be designed?






What do I want as purpose?  
Can I avoid the MDR?  
Can I afford the MDR?  
What options are there?



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Purpose: Catching monsters  
Effect: More physical activity  
Physical activity contributes to prevention of CVD, Diabetes, etc.




- Which is a derivative of physical activities

What if PG's intended purpose was defined as prevention?



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First Dutch Nintendo Switch game  
 Purpose: Team Building / Socializing of youngsters  
 Effect: More and improved communications  
 Side effect: Improved communication skills for autism!

What if TT's intended purpose was treatment of autism?


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## Some tips



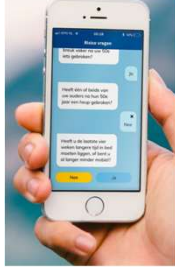
**MijnFertiCoach**

Sponsor







Healthy Bones App




Embedded in Portal



Other party's money



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## Clear intended purpose

**INSIGHT<sup>™</sup> ADHD**  
our behavior tracking app

**SKILL ASSIST**  
our online support services and call center

**Endeavor<sup>™</sup>**

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## FDA Permits Marketing of First Game-Based Digital Therapeutic to Improve Attention Function in Children with ADHD

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**For Immediate Release:** June 15, 2020

[Español](#)

Today, the U.S. Food and Drug Administration (FDA) permitted marketing of the first game-based digital therapeutic device to improve attention function in children with attention deficit hyperactivity disorder (ADHD). The prescription-only game-based device, called EndeavorRx, is indicated for pediatric patients ages 8 to 12 years old with primarily inattentive or combined-type ADHD who have demonstrated an attention issue. EndeavorRx is indicated to improve attention function as measured by computer-based testing and is the first digital therapeutic intended to improve symptoms associated with ADHD, as well as the first game-based therapeutic granted marketing authorization by the FDA for any type of condition. **The device is intended for use as part of a therapeutic program that may include clinician-directed therapy, medication, and/or educational programs, which further address symptoms of the disorder.**

“The EndeavorRx device offers a non-drug option for improving symptoms associated with ADHD in children and is an important example of the growing field of digital therapy and digital therapeutics,” said Jeffrey Shuren, M.D., J.D., director of the FDA’s Center for Devices and Radiological Health. “The FDA is committed to providing regulatory pathways that enable patients timely access to safe and effective innovative digital therapeutics.”

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# The dream of all

## Maker Of \$295 Prescription Video Game For Kids With ADHD To Go Public In Palihapitiya-Led SPAC Deal

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### It all seems a labyrinth



Above all



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# Some literature

**MDR and digital health**  
How to build MDR compliant applications

CHINO.IO

**Medical Device Software under the MDR**  
*Qualification and Classification of Software as a medical device*

Annette J. van Raamsdonk, LL.M.  
Senior Regulatory Affairs Consultant, Emergo  
TFHC, May 19<sup>th</sup> 2021

EMERGO

<https://www.chino.io/a/chino-io-ebook-medical-device-regulation-ehealth-applications>

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The practical step-by-step guide to turning ideas into (virtual) reality.  
Renee Luigies & Koen van den Hurk

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Thank you for your attention!  
and  
Good luck!

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<https://www.linkedin.com/in/renelugies/>

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