



The Challenges of Starting A Medical Device Co.

By Melissa K. Waugh, J.D., M.P.H.
Co-founder and CEO

Elcare Innovations, Inc.

A medical device company with a focus on emergency rescue devices for health care professionals and the general public

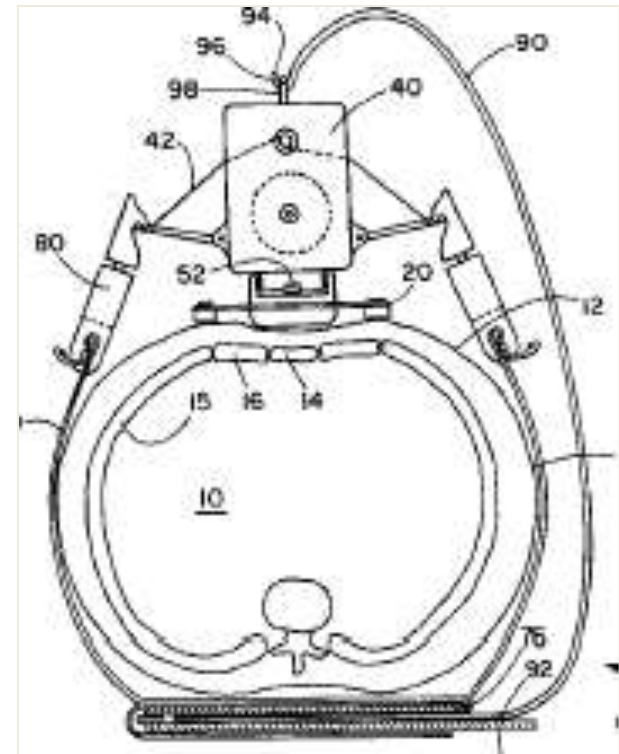
- ✓ Incorporated in Oct. 1997
- ✓ First **SBIR grant** in June 1998
- ✓ First **patent issued** in Jan. 2001
- ✓ First **device cleared for marketing by FDA** (510(k)) in Dec. 2001
- ✓ First full-time executive - April 2002

PAR

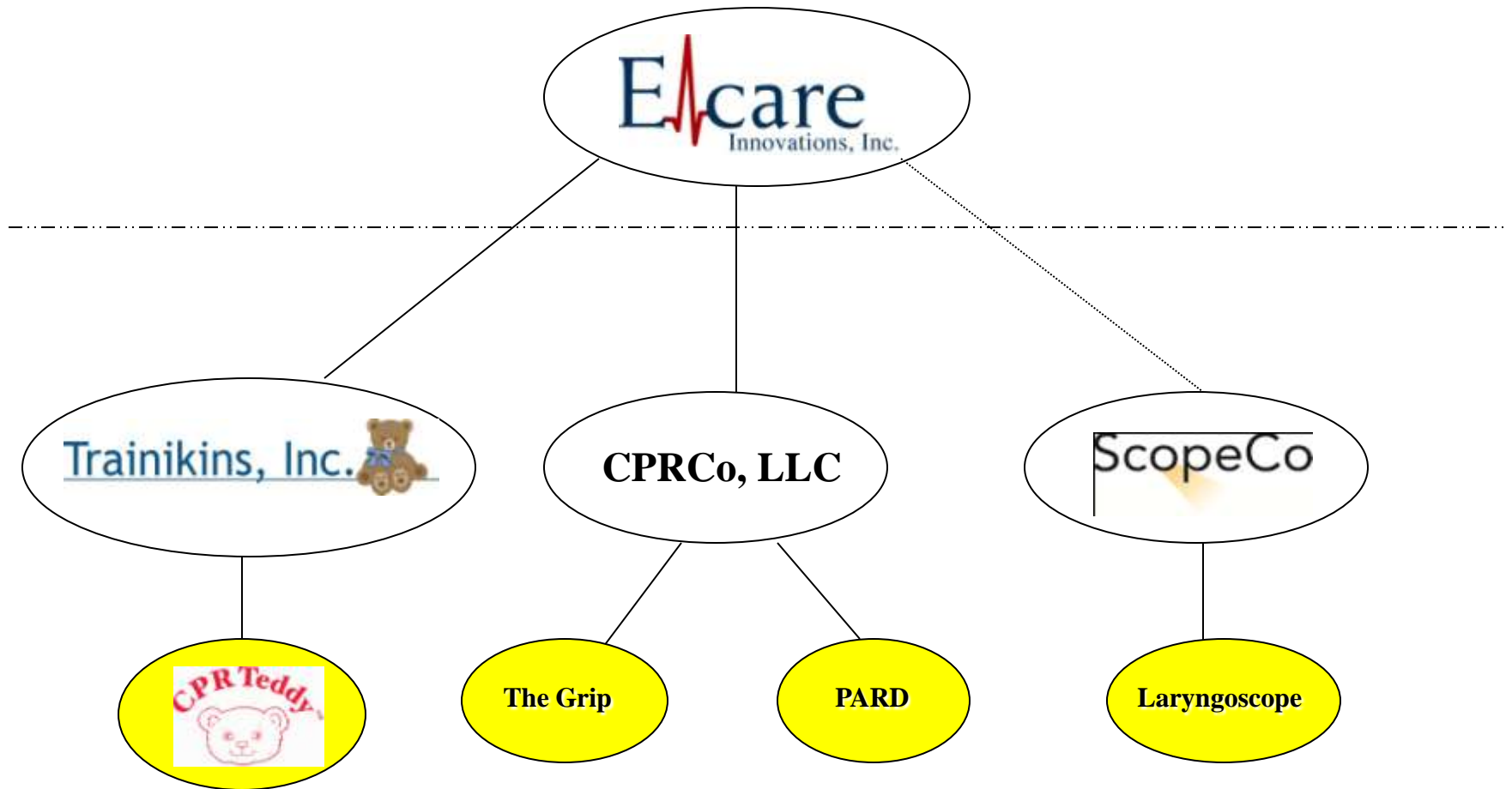
Portable Automatic Resuscitation Device



- Automatic sternal compressions with pause
- Abdominal compression or binding
- Decompression
- Disposable chest pad



Corporate Organization



**So you have a
great idea ...
now what?**

- **The Inventor's Notebook**
 - IP
 - FDA
- **The Business Plan**
 - Where you want to go and how to get there
 - How will you fund this adventure?
 - Local SBDC for training (www.sba.gov)
 - SCORE (www.score.org)
- **Avoid Scam Artists**
 - Invention Promotion Firms (www.ftc.gov)

Start Your Business

Business Entity Formation

- Sole proprietorship - default
- C Corporation
 - Authorized shares (beware in VA)
 - DE vs. your state
- S Corporation
 - IRS election to be taxed as a pass-through entity
 - No more than 100 shareholders
 - Pro-rata distribution of profits/losses
- Limited liability corporation (LLC)
 - Members

Other Issues

- **Name your business**
(SCC Clerk's Office 1-866-722-2551)
- **Business licenses and tax matters**
(www.scc.virginia.gov; Business One Stop -
www.dba.virginia.gov)
- **Insurance**
 - Product liability & Premises liability
 - Directors & Officers
 - Property & Business Interruption
- **Find a good accountant**
- **Find a good attorney**

Other Issues

- **Forming a Board**
- **Where to Office (home vs. leased space)**
- **Human Resources**
- **Raising Capital**
 - **Self-fund**
 - **Banks**
 - **Friends & Family**
 - **Angels**
 - **VC**

Intellectual Property

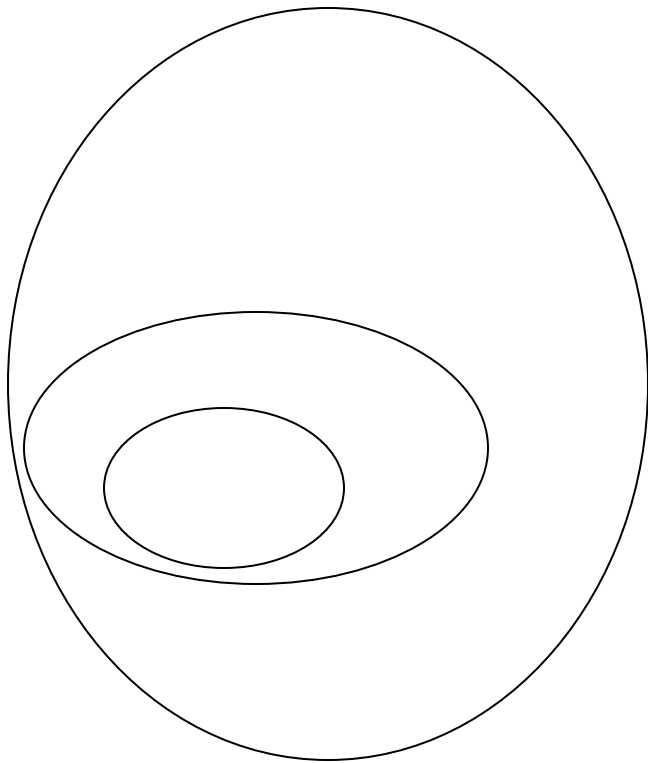
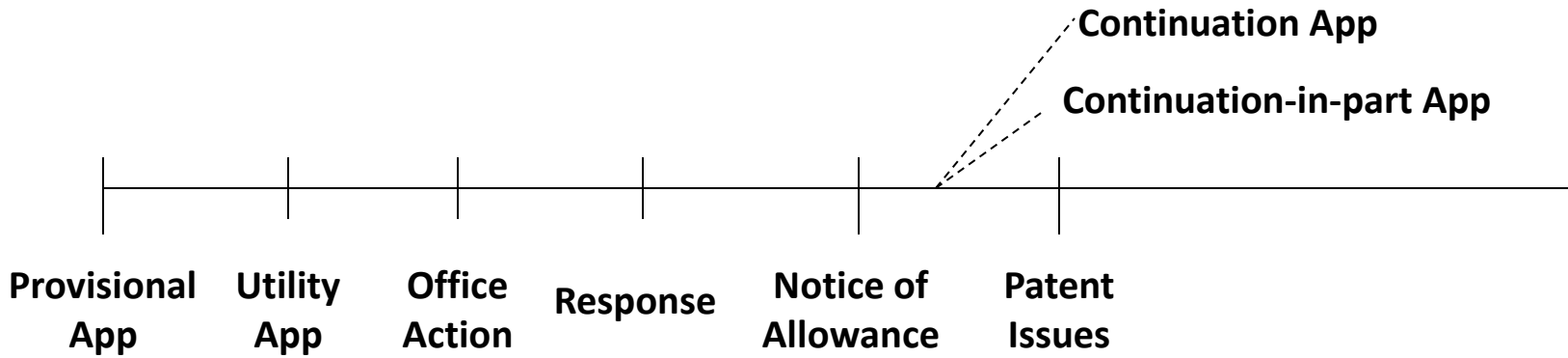
Intellectual Property

- **Federal** (U.S. Constitution; Federal laws; International treaties; case law)
 - Copyrights
 - Trademarks
 - Patents
- **State** (U.S. Constitution; State Constitution; State laws; case law)
 - Trade secrets
 - Right of Publicity
 - Moral Rights
 - Traditional Unfair Competition
 - Trademark dilution and misappropriation
- **Property rights in the intangible**
- **Balance between:**
 - Providing an incentive to create
 - Promoting competition through public access to new products and services

Types of Patents

- **Utility** (<6/8/95=17 yrs. from issue; >6/8/95=20 yrs. from filing)
 - For any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof
 - Provisional (no claims necessary; patent pending; 1 year)
 - PCT
- **Design** (14 yrs. from issue)
 - For a new, original, and ornamental design for an article of manufacture
- **Plant** (same as utility patents)
 - For anyone who invents or discovers and asexually reproduces any distinct and new variety of plant

1. Must fully-disclose the invention
2. Novelty Standard: It's not new if
 - a. the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
 - b. the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the application for patent in the United States . . .”
3. Non-obviousness standard: not obvious to a person having ordinary skill in the pertinent art as it existed when the invention was made---examiner can combine 2 or more prior art references.
4. “Useful” means the subject matter has a useful purpose and must operate to perform the intended purpose.



- 1. Independent Claim A
- 2. Dependent Claim B
- 3. Dep. Cl. C
- 4. Dep. Cl. D

A CPR Teddy Patent Claim

Claim 26:

- A. An apparatus for practicing human cardiopulmonary resuscitation (CPR)
- B. contained in a stuffed toy housing
- C. comprising a chest plate
- D. and back plate
- E. a compression depth sensor
- F. a compression depth indicator located in the CPR training aid and in the line of sight of the user, and
- G. a compression pacing indicator.

Claim 33: The apparatus of claim 26, further comprising (H.) auditory voice prompts

Claim 34: The apparatus of claim 33, (I.) wherein the voice prompts remind a user of the steps of CPR

Laryngoscope IP History

- **9/4/03**
 - Provisional patent filed
- **9/1/04**
 - Utility application filed
- **9/3/04**
 - PCT application filed
- **3/10/05**
 - Utility application pub.
 - US2005/0054903 A1
- **3/17/05**
 - PCT application pub.
 - WO 2005/023332 A2
- **4/19/05**
 - First Office Action by U.S. PTO
- **5/1/05**
 - International Search Report and Written Opinion Received
- **7/6/05**
 - Mtg. with Examiners at U.S.PTO
- **7/11/05**
 - Response to First Office Action
 - Amendments filed under PCT
- **7/27/05**
 - Notice of Allowability
- **12/2/05**
 - Continuation application filed
 - 11/292,828
- **1/31/06**
 - Patent issued (#6,991,604)

The FDA

Basic Regulatory Requirements



- Premarket Notification (510(k)), unless exempt, or Premarket Approval (PMA),
- Establishment Registration on form FDA-2891
- Medical Device Listing on form FDA-2892
- Quality System Regulations (QSR)
- Labeling requirements
- Medical Device Reporting (MDR)

Device Classification

- Assumes you have a “medical device”
- Class I, II, III
- Exemptions
 - Class I: Splints; knee brace; cane; crutch; tongue depressor; toothbrush; treadmill
- Determining your classification (e.g., C-DBL)
- Unclassified (e.g., The Grip)
- Not regulated (e.g., CPR Teddy)



Premarket Notification [510(k)]

Process by which most medical devices receive marketing clearance in the United States

- Must submit 510(k) to FDA at least 90 days before marketing a device, however, you need a letter of substantial equivalence from FDA to legally market the device
- This letter “clears” a device for marketing
- The 510(k) demonstrates to the FDA that the device is Substantially Equivalent (SE) to a legally marketed device that is not subject to Premarket Approval (PMA)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
5200 Corporate Boulevard
Rockville MD 20850

DEC 13 2001

Elroy Cantrell, D.O., Ph.D.
Elcare Innovations, Inc.
685 Elkins Lake
Huntsville, TX 77340

Re: K010526
The Grip
Regulatory Class: Unclassified
Product Code: 74 LIX
Dated: September 27, 2001
Received: September 28, 2001

Dear Dr. Cantrell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).



Substantially Equivalent

- The new device is SE if it is as safe and effective as the predicate device(s).
- A device is SE if, in comparison to a predicate device it:
 - has the same intended use as the predicate device; **and**
 - has the same technological characteristics as the predicate device; **or**
 - has different technological characteristics, that do not raise new questions of safety and effectiveness, and the sponsor demonstrates that the device is as safe and effective as the legally marketed device.

The Review Process

1. Log-in and assignment of K number
2. Division acceptance
 - Division of General and Restorative Devices
 - Division of Laboratory Devices
 - Division of Cardiovascular, Respiratory, and Neurological Devices
 - Division of Ophthalmic Devices
 - Division of Reproductive, Abdominal, Ear, Nose, and Throat and Radiological Devices
3. Reviewer assignment
4. FDA requests additional information
5. Administrative review
6. Decision letter issued

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