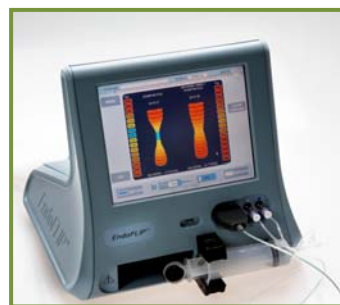


Innovation and Standards in Medical Device approvals

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Crospon Overview

- Founded Nov 2006
- 18 staff
- Electromedical products
- Product launch Q2-09



Medical Device Standards

- Standards not optional
- Safety versus performance in many instances
- Constantly changing !
- Constantly growing !

Routes to market

- Europe
- U.S.
- Canada
- Latin America
- All largely use the same standards or national variations

Europe

- Need an approved Quality system
 - Meet EN ISO13485 Standard
- Products must meet the Essential Requirements of Medical Device Directive (MDD)
- EU approvals more focused on device safety versus performance
- Horizontal versus Vertical standards

Europe (cont.)

- If you meet the *Particular Standard* for your device you are deemed to meet the MDD *Essential Requirements*
- There is not a Particular Standard for every product !
- Rely on Horizontal Standards and Essential Requirements (ER) assessment document
- ER assessment much more subjective

Standards testing

- Best use a third party
 - Impartial view
 - Pick a test house that is experienced in your technology
 - Better safety
 - Expensive
 - Certificates often requested by customers
 - Can be used in different territories

Europe CE Mark

- Technical File
 - Extensive reference to standards testing
 - Labelling
- Clinical testing
 - Significant uptick in requirements in new version of MDD
 - Meet EN ISO 14155
 - 14155 is very burdensome for simple low risk medical devices requiring customer preference testing

Relevant Standards (Electromed)

- Electrical Safety – EN 60601-1
 - V2 - ~160 pages
 - V3 - ~380 pages
- Electromagnetic Compatibility – EN60601-1-2
- Particular Standards e.g. EN 60601-2-x
 - e.g. *Medical Electrical Equipment- Particular requirements for the safety of endoscopic equipment*

But there's more ..

- ISO14971 - Risk Management
- IEC62304 – Software Lifecycle
- Biocompatibility – ISO10993
- EN60601-1-6 – Alarms
- EN60601-1-8 – Usability
- A “standard” or a “requirement”



Europe - Summary

- Knowledge of standards requirements needs to be built in up front in product specifications
- Standards must be designed in and not tested in !
- Particular standards where they exist are very helpful
- Can combine requirements from different Particular Standards to build the case of conformance to Essential Requirements

On a more positive note ..

- Once approved in Europe
 - Cert of Free Sale opens approvals process into Latin America
 - Strong leverage for Canada and Australia
- Having test reports helps in Notified Body device reviewer interactions
 - Common framework for interaction (more facts than opinions)
 - Third party credibility

U.S. Device Approvals

- 510k (similar to predicate)
- PMA (safety and efficacy)
- FDA increasingly adopting/ demanding standards though to a lesser degree than EU
- Abbreviated 510k program
- Testing before submission or product launch ?
- FDA Recognized Consensus Standards List
 - Sometimes not the most current version of standards

U.S. Device Approvals (Cont.)

- Meeting IEC 62304 for software development can reduce level of documentation required to be submitted
- Increasing visibility of standards in 510k cover sheet

SECTION I		UTILIZATION OF STANDARDS			
<small>Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.</small>					
	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					

Some general comments

- Medical Devices is a highly regulated sector
- Regulation level is increasing
- Approval costs are increasing dramatically
- Who writes standards ?
- Proliferation of standards
- Can limit the scope of a design
- Safety versus Useability versus Market Acceptance

Conclusion

- Standards drive us towards safer product designs
- An essential element of the design specification process
- If you're not comfortable with standards , the medical device business is not for you !