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Medical computers from the manufacturer's viewpoint

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The recent surge in the scope of computer applications in medical care has brought with it great strides in patient care, but it has also created a variety of concerns to manufacturers of medical software. The spate of product liability suits, with its potentially crippling effects in terms of product development, makes it increasingly vital that manufacturers engage in prospective planning, to anticipate problems and take steps before legal action ensues, so that all parties—the manufacturer, the hospital, and ultimately, the patient—benefit from the availability of new technology. The Food and Drug Administration (FDA) and Congress are similarly grappling with the implications of this new technology, to assure that patient care is not compromised by products that have not yet been fully tested. The tension between the desire to make technology available to the public and the realities of the present regulatory and litigious climate is the key dilemma facing manufacturers of medical software.

Medical software; FDA regulation; Product liability; Legal; Medical devices

1. Introduction

The surge in the scope of computer applications in medical care has brought with it great benefits in terms of patient care, but it has also raised a variety of concerns regarding the implications of this new technology. The intent of this paper is to highlight some of the most salient issues of concern to manufacturers of computer systems for the health care industry.

The starting point is whether software is subject to FDA regulation as a 'medical device' under the Medical Device Amendments of 1976. If so, what steps are necessary to gain FDA approval? The second area of concern involves liability issues, including theories of liability, warnings, the role of standards, and legislative approaches to solving the liability crisis. Third, which is the optimal

strategy for the marketing of computer components—the sale, lease, or licensing of software and hardware? With these broad parameters in mind, let us turn to the regulatory side of the picture.

2. Regulatory issues

The Medical Device Amendments to the Federal Food, Drug and Cosmetic Act [1], and implementing regulations, extend federal regulation to the design, manufacture, testing, scale, and to a certain extent, even the storage and use of medical devices. A 'medical device' is broadly defined to include every product, other than drugs, used in the diagnosis, treatment, or prevention of disease in humans or animals [2]. Although the definition includes devices used in connection with animal diseases, most of the implementing regulations have focused only on devices used in connection with disease in humans.

Both hardware (instrument, apparatus, imple-

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ment, machine') and software ('contrivance') which are "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man" or "intended to affect the structure or any function of the body" constitute medical devices [3]. Many computer-related products are medical devices because they come within the scope of the definition as a "component, part, or accessory." These include products from secondary sources and from manufacturers other than the supplier of the primary device.

Software that actively manipulates patient data and uses the results to control a change in device operation or patient treatment, is considered to be a medical device for purposes of the Act. On the other hand, systems for passive recording, retrieval, and display of medical history data, encoding, storage, and display of medical textbooks and articles, and encoding of electromagnetic transmission will not be regulated [4].

Manufacturers of software deemed to be medical devices (unless qualifying for an exemption, such as for investigational use, which must be approved in advance [5]) must comply with a variety of controls. These include: establishment registration, describing the 'manufacturer'; device listing, describing every device manufactured by each registered establishment; good manufacturing practice regulations, describing safe manufacturing, and quality control requirements; pre-market notification, under which the FDA must be notified ninety days in advance before marketing a new device not substantially equivalent to an old classified device; compliance inspections by the FDA; prohibitions against misbranding and adulteration; procedures under which FDA may ban or detain dangerous devices.

The next question that arises is through which route should a manufacturer seek to clear the regulatory barrier in marketing a system—pre-market approval (PMA) or premarket notification (510(k) [6])? The simplest, [6] least costly, and fastest way to get a new device on the market is to file a 510(k) notification, and for these reasons, the 510(k) submission has become the option of choice wherever possible [7].

There are several advantages to the 510(k) route.

On its face, it is far easier to satisfy than seeking premarket approval under section 515 of the Amendments. Unlike the latter, safety and effectiveness data are not explicitly required, only a showing of "substantial equivalence" to a pre-existing device (i.e. that the device is "just an extension of existing systems"). Under 510(k), a company can normally obtain FDA acceptance without clinical trials or, indeed, even without developing a physical prototype. The chances of avoiding FDA disapproval of the marketing of the device improve significantly with a 510(k), and 510(k) is more likely to result in a speedy, as well as a favorable, disposition than a PMA.

There may be situations where a PMA could be advantageous, as, for example, where a company has already gathered safety and effectiveness data and, thus, might find its market position vis-a-vis competitors stronger if it could establish that a specific new device requires a PMA. The 510(k) route might also be less desirable if patent infringement looms as a potential issue. Although the FDA has explicitly taken the position that "substantial equivalence" to a specified pre-amendment device is not based on patentable characteristics, some practitioners recommend the addition of a statement on all 510(k) notices that claims of substantial equivalence is intended to have no bearing on the resolution of patent matters [8].

The submission of a 510(k) application does not, however, preclude the FDA from seeking safety and efficacy data. Several manufacturers of Nd:YAG lasers, for example, have been advised by the agency to file a hybrid 510(k), to include such data, under a catch-all provision allowing the agency to "seek any additional information it deems necessary". In view of increasing criticisms by a House Subcommittee [9] and the General Accounting Office [10] challenging FDA's use of 510(k)s without explicit safety and effectiveness determinations, the FDA will in all likelihood increase its demands for such notifications, particularly with respect to Class III devices [11].

The entire issue of software regulation in health care is currently under review in Congress. On 21 April 1986, hearings were held [12] before the House Science and Technology Subcommittee to assess whether further regulation is necessary to

protect the public. The concern of many of the witnesses, however, was that the tide of regulation might indeed stifle innovation and the growth of technology to the detriment of patient care.

3. Liability issues

To win a health care product liability suit, the plaintiff must show that the product was defective, that the product had not been altered since its manufacture, and that the defect caused the injury. The first element is whether there is a 'product.' The distinction between what is viewed as a 'product' vs. a 'service' is pivotal—warranty law applies *only* to 'products,' not 'services' (such as medical care). If viewed as a 'product,' a 'strict liability' standard will most likely apply; but if viewed as a 'service,' the manufacturer will likely be held to a 'negligence' standard.

The second element is that there be a 'defect.' There are three ways in which a product may be adjudged defective—through improper manufacturing (unintended aberration in the manufacturing process), improper design (manufacturer's conscious choice to design a product in certain manner), or failure to warn of dangers in the product. The latter may constitute a defect even in the absence of a physical imperfection in the product.

Finally, evidence must show that the defect is attributable to the manufacturer rather than to the acts of a third party, and that the injuries suffered were caused by use of the defective product. If the hospital misuses or changes a product in any way, the hospital, not the original manufacturer, would be held responsible. An exception might exist if the manufacturer told the hospital that the product could or was intended to be used as an attachment to another product.

The issue of warnings is a highly litigated area in the product liability field as well as of major concern to the FDA. The question of failure to warn arises with respect to whether there is a 'defect.' A manufacturer has a duty to warn of those dangers that are known or reasonably foreseeable at the time of marketing. That duty extends to providing directions or instructions that

describe how to avoid the risk or danger associated with a product and the means for using the product safely. The courts generally hold the manufacturer to the skill and knowledge of an expert in the field, and charge him with the duty of keeping abreast of scientific knowledge and new developments in the field.

To arrive at a determination that a product is unreasonably unsafe because of inadequate warnings or instructions, the trier of fact must find that, at the time of manufacture, the likelihood that the product would cause claimants harm, and the seriousness of the harms, rendered the manufacturer's instructions inadequate, and that the manufacturer could have and should have provided such warnings or instructions [13]. In addition to dangers known or foreseeable at the time of marketing, the manufacturer has a duty to act with reasonable care upon learning of defects or risks associated with products already in the stream of commerce, and to make prudent efforts to inform product users of newly discovered dangers.

Medically related products liability cases often center on the manufacturer's failure to adequately warn physicians of possible dangers. The plaintiff must show that the warning was unreasonable under the circumstances and that an adequate warning would have altered the physician's conduct. The court (and, in its own context, the FDA) will look to product inserts, labels, instruction manuals, letters from companies to physicians, oral representations by salespersons, the medical device itself, the Physician's Desk Reference, and other manufacturer sources to show what representations were made by the company to the physicians. Thus, otherwise adequate warnings may be diluted by the manufacturer's total marketing plan.

The purpose of a warning is to eliminate, or significantly reduce, risk of injury from a hazard for which there is no design alternative that will accomplish the same purpose. Since a warning must induce conscious action, or inaction, on the part of the user, the message should contain three elements: the nature of the hazard, the risk of injury to be avoided, and the action that must be taken to eliminate the risk of injury.

The issue of sufficiency of a warning is typi-

cally a jury question, to be resolved based upon factors such as the dangerous nature of the product, how the product is used, the form and intensity of the warning, the burden of providing a warning, and the probability that the warning will be communicated to those who may foreseeably use the product, and in a way so that the user population will likely understand the nature and extent of the danger. In sum, warnings, to be effective, must be selective and call the consumer's attention to a danger that has a real probability of occurring and whose impact will be significant [14].

Aside from certain isolated cases of statutory regulations (e.g. the warning on cigarette packages), the actual wording, size, graphics, etc., as well as identification of all the hazards, are left to the creativity of the manufacturer. By and large this is true for other governmental regulatory activities, voluntary consensus standards (e.g. International Standards Organization, American Society of Mechanical Engineers), and for those few corporations that have active labeling programs (e.g. Westinghouse, FMC Corp.).

Standards are considered floors, not ceilings, with respect to a manufacturer's duty (i.e. they reflect the *least* the manufacturer should do in designing, producing, and marketing a product). The courts have, for the most part, uniformly held that a careful manufacturer would use a higher level of care than that represented by the standard, where other foreseeable uses and misuses of a product would so dictate. This reasoning applies as much for applicable federal regulatory standards as it does for voluntary consensus or industry standards.

Failure to adhere even to an applicable voluntary or industry standard is tantamount to liability per se but adherence to a standard will not automatically absolve a manufacturer of liability. It becomes a question of fact for a jury to decide whether or not a manufacturer should have used a higher standard [15].

Where a standard provides for a specific *design requirement*, or a specific *test requirement* (e.g. the crush distance for a specific load applied to a car roof), however, the manufacturer can at least argue that the risk/utility considerations inherent in the

design or test requirements of the standard represents the appropriate tradeoffs. If a manufacturer has considered all of the competing considerations that govern selection of a design or test requirement and has explicitly concluded that the standard represents the appropriate balance, then this can be an effective response to a plaintiff's contention that the manufacturer can deflect the argument away from product design to those responsible for writing the standard [16].

There are three major theories of liability in products cases. First, is breach of warranty. There are two types of warranty—express and implied. An express warranty is any affirmation of material fact upon which a customer relies. Express warranty applies when the manufacturer has explicitly guaranteed that the product is able to meet certain standards. This generally occurs in contracts. A contract with a manufacturer may state, for example, that the manufacturer will sterilize and seal all products and that they will arrive in an appropriate sterilized condition. If infection occurs due to the product (and not due to improper handling by the hospital staff), the manufacturer may be found liable for breach of an express warranty.

In contrast, an implied warranty derives by implication or inference from the nature of the transaction, or from the relative situation or circumstances of the parties. It springs from the presumed intention of the parties. Stated another way, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind" (UCC, §2-314). A 'merchant' is generally defined as someone who deals in goods of the kind or otherwise by his occupation holds himself out as having special knowledge or skill to the practices or goods involved in the transaction. It should be noted that a recent case, applying strict liability to used products, has greatly expanded the scope of those that are considered 'merchants' and thus, at least in Massachusetts, it appears that a large number of sellers who previously had been immune from strict liability will now become potential defendants [17].

The second major theory of liability is negligence. Negligence is a violation of the duty to use

care with respect to a person to whom a duty of care is owed. It occurs whenever the manufacturer does not take reasonable care in producing the product. Negligence in products cases usually involves failure to warn or to warn adequately against foreseeable dangers, a failure to fully inspect or test, a failure in either design or production to comply with standards imposed by law, or to live up to the customary standards of the industry.

Yet a third ground for liability is strict liability. The theory of 'strict liability in torts' is very similar to 'breach of warranty' under the Uniform Commercial Code. In neither case the plaintiff must prove negligence. Under breach of warranty, all plaintiff must prove is the breach of an implied warranty, the injury, and a causal connection between the two. Thus, while only four states have not adopted the doctrine of 'strict liability in tort,' they accomplish the same results.

The Second Restatement of Torts, Sect. 402A, published by the American Law Institute in 1965, has been widely adopted by the courts as a description of the rules of strict tort liability. That section provides that:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
 - (a) the seller is engaged in the business of selling such a product, and
 - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in subsection (1) applies although
 - (a) the seller has exercised all possible care in the preparation and sale of his product, and
 - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller [18].

Besides situations where products are found to be "unreasonably dangerous," sellers have been held liable in strict tort when their product has

failed to conform with their public representations of its quality:

One engaged in the business of selling chattels who, by advertising, labels, or otherwise, makes to the public a misrepresentation of a material fact concerning the character or quality of a chattel sold by him is subject to liability for physical harm to a consumer caused by justifiable reliance upon the misrepresentation, even though:

- (a) it is not made fraudulently or negligently, and
- (b) the consumer has not bought the chattel from or entered into any contractual relation with the seller [19].

The scope of liability under a strict product liability theory appears to have been widening with the past year or two. See, for example, *Ferragamo v. Massachusetts Bay Transit Authority* [20] (transit authority that sold old trolley car 'as is' for scrap metal held strictly liable to a scrap worker who was killed by poisonous gas while dismantling the cars), expanding the doctrine to used products; *Kelly v. R.G. Industries* [21] (gun manufacturer and retailer) may be strictly liable to an innocent person killed or injured by a 'Saturday Night Special,' not because handguns are "unreasonably dangerous," but because this type of gun has "little or no legitimate purpose in today's society" (i.e. solely on the basis of public policy).

There may also be differences in what the plaintiff may tell the jury, depending on whether suit is brought in strict liability or negligence. The Nevada Supreme Court, in *Jeep Corp. v. Murray*, [22] held that in a strict liability action the jury may be told that the manufacturer changed the product after the plaintiff's accident despite a state statute that such evidence could not be used to prove a defendant's "culpable conduct." The court ruled that this refers *only* to negligence and not to strict products liability.

Despite the gloomy picture, from the perspective of the manufacturer, the courts have not left the manufacturer completely helpless. More and more courts are allowing defendants in 'strict products liability' cases to reduce awards by as-

serting plaintiff's 'comparative negligence' as a defense. See, for example, *Vannoy v. Uniroyal Tire Company* [23] (strict liability suit, based on explosion of a tire; the court, citing at least seven other courts which have applied comparative negligence principles to strict liability actions, concluded that there should be no difference between the way the cause of the accident is assessed in regular negligence cases and in strict products liability cases).

Further, it should be realized that even under the theory of strict liability in tort, the mere fact that an accident involving a medical device has occurred is not a sufficient basis to impose liability since the manufacturer is not an insurer of his product. It is the concept of 'defect' that marks the zone of liability.

The liability crisis has sparked debate as to its causes, existence and solutions in a wide variety of circles. The Reagan administration, on 30 April 1986 sent Congress three proposals to limit damage awards in personal injury lawsuits and to revamp product liability law, in response to what has been described as a crisis in the liability insurance industry. The proposed legislation would override current state laws dealing with product liability and limit payment for "pain and suffering" and punitive damages, limit lawyers' contingency fees, and would eliminate the concept of "joint and several liability," which makes everyone who is responsible for an accident liable for the entire damage award regardless of their degree of fault. It would also permit damage awards to be paid in installments, rather than in lump sums [24]. Similarly, Proposition 51 was passed in the June 1986 primary in California limiting "joint and several liability" of defendants to only "pain and suffering" they caused directly. Previously, joint and several liability, which evolved through court decisions and not statute, could be used to force a defendant with as little as 1% of responsibility for an injury to pay 100% of the damages if other defendants cannot pay their share. Thus, this represents a major change in California law and portends a trend already manifest in legislation proposed in Michigan and New York, and 38 other states.

4. Marketing strategy issues—sale, lease, and licensing of hardware and software

A key issue of risk management is whether to sell outright, lease, or license computer systems. The optimal choice, at least with respect to the software component, depends on whether medical software is considered a 'product' ('strict liability' standard) or a 'service' ('negligence' standard). Medical computer programs will most likely be treated as 'products' by the courts, subjecting their manufacturers to strict liability for any defects in the program that cause injury [25]. This view is consistent with the Ninth Circuit's analysis in *RRX Industries v. Lab-Con, Inc.*, where the Court stated that "the employee training, repair services and system upgrading were incidental to sale of the software package and did not defeat characterization of the system as a good" [26].

The issues of ownership and control are crucial in distinguishing products from services. Once a clearly defined sale or similar transaction takes place, whether through a lease, gift, or trade, the manufacturer's exposure to liability is established. The actual risk of liability, however, varies, based on the amount of control retained by the manufacturer.

In reference to software design, if the hospital purchases the programmer's time on an hourly basis, the hospital is more likely to be considered a manufacturer than a purchaser. If the hospital buys the rights and usage of the particular programmer, it is more likely to be considered a purchaser. If the hospital, in attempting to recoup the cost of developing a system, sells the system to another user (e.g. charges individual departments for such usage), it probably will be considered a manufacturer. Thus, there can be more than one manufacturer for liability purposes.

Involvement of the purchaser (hospital) in design, application, and updating is desirable from the manufacturer's standpoint, both in terms of reduction in liability consequences (joint and several liability) and on the issue of allocation of damages. This, of course, assumes that the system user and provider are separate entities. Professionals and hospitals are most likely to be held liable for the errors of systems attributable to their

own efforts, at least when they are the source of a faulty program.

The optimal solution from the manufacturer's perspective appears to be the sale of the hardware, and the licensing of the software component. Although leasing medical hardware would, at first glance, appear to provide advantages in terms of greater exclusivity and control of the product, such benefits could be attained through patents to protect design characteristics; through contractual provisions, providing for the confidentiality of the existence or terms of contracts, training and other materials; and through the protection of trade secrets with far less exposure to liability. Thus, on balance, the lesser liability risk is to sell rather than lease the hardware.

Software licensing has distinct advantages over the sale of the program. Licensing conveys a right of use, without passing title of the software or even of the right to copy the program. While software can be sold, the usual transaction involves a license to use. In its simplest form, a software license is a contract by which the licensor grants the licensee permission to use the software in certain ways subject to certain restrictions. Under such an agreement, the licensor not only retains full ownership of the software, but can restrict the licensee's use of the software in many critical respects. These restrictions are used to achieve an important goal—protection of the potential market for the software package [27].

The advantages of licensing are protection of proprietary rights through:

- (1) Protection of confidentiality by contract.
- (2) Preservation of copyright without making the work subject to the 'first sale' doctrine (i.e. that where the end user (hospital) is also the owner of the program copy, the end user has the exclusive right to sell, transfer, or otherwise dispose of title to the copy. Thus, the manufacturer, not the hospital, retains the right to sell, transfer, etc.
- (3) May help avoid application of UCC implied warranty provisions.
- (4) Binds user to restrictions on product use even if an infringing user does not sign and return the agreement, the manufacturer may sue for misappropriation. In suit for misappropriation a significant factor will be to convince the court that trade secrets protection is being seriously pursued.

Thus, software licensing provides distinct advantages over the alternatives.

5. New trends

The maze of federal regulations, legislative proposals, and the serious potential for personal injury lawsuits with large damage awards makes development of a comprehensive risk management program vital, both to assure compliance with federal standards and for the protection of the manufacturer and the public safety alike.

While no assurances can be made that legal action or liability can be avoided, prospective planning can clearly ensure that steps may be taken to minimize the risk. The best guarantee is, of course, a safe product. By ensuring optimum safety and reliability of computer hardware and software, the manufacturer, the hospital, and, ultimately, the patient may all benefit from the availability of new technology. This is the final objective of regulatory/public health agencies such as the FDA, the manufacturer, and the ultimate user.

References

- [1] 28 U.S.C. §301 et seq.
- [2] 28 U.S.C. §201 [301], (h) (2).
- [3] 28 U.S.C. §201 (W) (2)&(3).
- [4] ———, "FDA Software Regulation Guidelines Bared," National Report: Computers and Health, Vol. 5, No. 21, 8 March 1985.
- [5] See §360 j (g)
- [6] 21 and 28 U.S.C. §360 (k) (1982).
- [7] Jonathan S. Kahan, Premarket approval versus premarket notification: different routes to the same market, *Food Drug Cosmetic Law J.* 39 (1984) 510–514.
- [8] Kahan, at 520; Barron, Rappaport and Johnson, Medical device and patent laws clash? *Food Drug Cosmetic Law J.* 34 (1979) 304–318.
- [9] Staff of House Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, 98th Cong., 1st Sess., Report on Medical Device Regulation: The FDA's Neglected Child 37 (Comm. Print 1983).
- [10] Report to the Congress by the Comptroller General, Federal Regulation of Medical Devices—Problems Still to be Overcome 56 (30 September 1983).
- [11] Kahan, at 524.
- [12] House Science and Technology Subcommittee Hearings, 21 April 1986.

- [13] Miller, et al., Potential liability for transfusion-associated AIDS, *J. Am. Med. Assoc.* 253 (1985) 23 at 3420.
- [14] For a detailed analysis of the issue of warnings, see generally Phelan & Ross, Co-chairmen, *Product Liability: Warnings, Instructions, and Recalls* (Practising Law Institute, New York, 1984)
- [15] *Ibid.*, at 165.
- [16] *Ibid.*, at 165-166.
- [17] *Ferragamo v. Massachusetts Bay Transit Authority*, No. S-3723, Mass. Supreme Court, 8 August 1985.
- [18] *Restatement (Second) of Torts* § 402 A (1965).
- [19] *Restatement (Second) of Torts* § 402 B (1965).
- [20] *Ferragamo*, op. cit.
- [21] Misc. No. 20, Maryland Court of Appeals, 3 October 1985.
- [22] No. 15354, 29 October 1985.
- [23] Idaho Supreme Court, No. 5529, 22 November 1985.
- [24] ———, Reagan sends liability proposals to congress, *Health Lawyers News Rep.* 14 (5) (May 1986).
- [25] V.M. Brannigan and R.E. Dayhoff, Liability for personal injuries caused by defective medical computer programs, *Am. J. Law Med.* 7:2 (1981) 556.
- [26] *RRX Industries v. Lab-Con Inc.*, 772 Fed 2d 543 (9th Cir. 1985).
- [27] M.D. Scott, *Computer Law* (Wiley Law Publications, 1985).

Appendix: FDA device classes

Sec. 513 [360c] (a) (1) There are established the following classes of devices intended for human use:

(A) Class I, General Controls

(i) A device for which the controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance, but because it—

“(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and (II) does not present a potential unreasonable risk of illnesses or injury,

is to be regulated by the controls referred to in clause (i).

(B) Class II, Performance Standards

A device which cannot be classified as a class I device because the controls authorized by or under section 501, 502, 510, 516, 518, 519, and 520 by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, for which there is sufficient information to establish a performance standard to provide such assurance, and for which it is therefore necessary to establish for the device a performance standard under section 514 to provide reasonable assurance of its safety and effectiveness.

(C) Class III, Premarket Approval

A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 are sufficient to provide reasonable assurance of the safety and effectiveness of the device and (II) cannot be classified as a class II device because insufficient information exists for the establishment of a performance standard to provide reasonable assurance of its safety and effectiveness, and

(ii) (I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury, is to be subject, in accordance with section 515, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

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