NEMA

Setting Standards for Excellence

ROBERT G. BRITAIN
Vice President, Medical Products

8803 '01 SEP 20 A9:21

September 19, 2001

Dockets Management Branch
HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket Number 01D-0281

To Whom It May Concern:

On behalf of the Diagnostic Imaging and Therapy Systems Division of the National Electrical Manufacturers Association, I am pleased to submit comments relative to the Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Draft Guidance for Industry and FDA Staff.

NEMA, the National Electrical Manufacturers Association, is the nation's largest trade association representing the electro-industry. NEMA's Diagnostic Imaging and Therapy Systems Division represents more than ninety-five percent of the nation's manufacturers of X-ray imaging, computed tomography, diagnostic ultrasound, radiation therapy, magnetic resonance imaging, and nuclear imaging equipment. In addition, the division represents manufacturers of picture archiving and communications systems.

NEMA strongly supports national implementation of globally harmonized processes. NEMA is encouraged by FDA's efforts to establish a Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures and applauds the FDA for taking coordinated steps with Australia, Canada, and the European Union to implement GHTF Guidance. NEMA offers the following comment on the proposed FDA Pilot Program:

Table 1 Candidate Devices:

Because of the very low volume of submissions of fluoroscopic X-Ray 510(k) s, NEMA believes that limiting the diagnostic imaging devices eligible for the pilot program to fluoroscopic X-Rays and bone densitometers may not provide a sufficient number of submissions

National Electrical
Manufacturers Association

1300 North 17th Street, Suite 1847
Rosslyn, VA 22209
(703) 841-3241
FAX (703) 841-3341
bob_britain@nema.org

01D-0281

D
C 2

necessary to evaluate the Pilot Program. Therefore NEMA suggests adding the following additional imaging modalities: computed tomography (CT) scanners and magnetic resonance imaging devices.

NEMA Member Participation:

In order to support the FDA objective to evaluate the Pilot Program NEMA will be strongly encouraging its members to participate in the Pilot Program.

Global Harmonization:

NEMA is committed to further application and use of the processes and principles developed by the GHTF, to which the participating representatives of FDA make valuable contributions. NEMA believes that this Pilot Program would further promote the overall goal of achieving a unified worldwide approach to product approvals for market access. To that end NEMA will make a recommendation, at a later date, for an additional globally harmonized alternative product review process.

NEMA is pleased to submit these comments relative to the agency's final rule on the Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Draft Guidance for Industry and FDA Staff. NEMA looks forward to working with the agency toward achieving efficient global harmonization.

Sincerely,

Robert L. Britain

National Electrical
Manufacturers Association
www.nema.org

1300 North 17th Street, Suite 1847
Rosslyn, VA 22209
(703) 841-3200
FAX (703) 841-5900

Align top of FedEx PowerShip Label here.

ORIGIN ID: NDVA (703) 841-3284
HIRAM ALFONSO
NEMA
1300 NORTH 17TH STREET
SUITE 1847
ARLINGTON, VA 22209

SHIP DATE: 19SEP01
SYSTEM #0637647 / CAFE2063
ACTUAL WGT: 0.2 LBS SCALE
ACCOUNT #: 020032820

FedEx

FedEx Account Number

TO:

DOCKETS MANAGEMENT BRANCH
HFA-305
5630 FISHERS LANE, ROOM1061
ROCKVILLE, MD 20852

REF: 0390-9000

NEMA

National Electrical Manufacturers Association
1300 North 17th Street, Suite 1847 Rosslyn, VA 22209